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No._____

In The

Supreme Court of the United States

October Term, 1999

CENTURY CLINIC, INC. and
KATRINA TANG, M.D. and H.M.D.,
Petitioners,

-v-

UNITED STATES OF AMERICA,
Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

Wm. Bradford Reynolds
(Counsel of Record)
Stephen Weissman
COLLIER, SHANNON, RILL
& SCOTT, PLLC
3050 K Street, N.W., Suite 400
Washington, D.C. 20007
(202) 342-8400

Thomas C. Bradley
SINAI, SCHROEDER, MOONEY
BOETSCH & BRADLEY
448 Hill Street
Reno, NV 89501
(702) 323-5178

Attorneys for Petitioners

117 pp

QUESTIONS PRESENTED

1. Whether a plaintiff in a civil contempt proceeding may satisfy its heavy burden of proving by "clear and convincing evidence" a violation of a court-ordered consent decree by "*reasonably satisfying* the factfinder that it is highly *probable* the ultimate fact at issue happened" when the Supreme Court and numerous courts of appeals have defined "clear and convincing evidence" to require substantially more?

2. Whether a federal administrative Agency has met its burden of proving contempt of a court order by "clear and convincing" evidence by relying exclusively for its proof on an uncorroborated and materially flawed tape recording by an Agency official which omits a crucial part of the relevant conversation?

3. Whether the court of appeals erred under *Universal Camera Corp. v. National Labor Relations Bd.*, 340 U.S. 474 (1951), by finding that the administrative Hearing Officer's decision was supported by "substantial evidence" when the Court of Appeals failed to consider record evidence undermining and contradicting the only purported evidence supporting the Hearing Officer's decision?

PARTIES TO THE PROCEEDINGS

The parties to the proceedings below were:

Appellant (Petitioner herein): Century Clinic, Inc.

Appellant (Petitioner herein): Katrina Tang, M.D. and H.M.D.

Appellee (Respondent herein): United States of America

RULE 29.6 STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Petitioners state as follows:

Petitioner Century Clinic, Inc. is a corporation incorporated under the laws of the State of Nevada. Century Clinic is a privately held corporation and has no subdivisions or affiliates that have issued shares to the public.

Petitioner Katrina Tang, M.D. and H.M.D., is an individual having no majority corporate ownership interests.

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PETITION FOR WRIT OF CERTIORARI

Petitioners, Century Clinic, Inc. and Katrina Tang, M.D. and H.M.D., respectfully petition for a writ of certiorari to review a judgment of the United States Court of Appeals for the Ninth Circuit.

OPINIONS BELOW

The opinion of the court of appeals, *see* Appendix ("Apdx.") A, is not reported. The district court's decision adopting the report and recommendation of the United States Magistrate Judge is not reported, *see* Apdx. B, nor is the Magistrate Judge's report and recommendation. *See* Apdx. C. The decision of the Hearing Officer for the Food and Drug Administration (also not reported) is attached as Apdx. D.

JURISDICTION

The court of appeals entered its judgment on July 22, 1999, and a timely petition for rehearing was denied on September 14, 1999. *See* Apdx. E. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1) (1988).

STATUTORY PROVISIONS INVOLVED

Section 360j(g) of Title 21 of the United States Code, 21 U.S.C. §360j(g) (1988), which is reproduced at Apdx. F.

STATEMENT OF THE CASE

This case raises important questions concerning the appropriate definition of "clear and convincing" evidence in proceedings alleging contempt of a court order, as well as in general. The court of appeals' affirmance below of the district court's and administrative Hearing Officer's decisions -- which defined "clear and convincing evidence" using a mere "highly probable" standard -- is in irreconcilable tension with decisions of this Court and other circuits which have defined the "clear and convincing" evidence standard to require significantly more than the standard of proof adopted in this case and elsewhere applied by the Ninth Circuit.

This case also brings to the Court another issue of fundamental importance: whether a federal administrative Agency can meet the heightened "clear and convincing" evidentiary standard solely through the presentation of an unauthenticated, untested, partially garbled, and uncorroborated tape recording created by an undercover official of the very Agency which has accused the Petitioners of contempt, which recording was, by design, incomplete. The demanding burden imposed by the "clear and convincing evidence" standard compels that the answer to this question be "no".

I. Factual Background

Since 1984, Petitioners Century Clinic and Dr. Katrina Tang, M.D. and H.M.D., have provided homeopathic treatments to innumerable patients. Dr. Tang is a fully accredited doctor of medicine who is licensed to practice

Homeopathy in Nevada.[1/] At all relevant times, she has practiced at the Century Clinic, which is located in Nevada.

In the early part of 1990, the Food and Drug Administration ("FDA") targeted Century Clinic and its medical team for investigation based on what the Agency suspected was improper use of an electro-dermal screening device, called the EAV Dermatron. The EAV Dermatron, a device which was developed overseas and had been much studied by medical scientists in foreign countries, has proven to be effective in providing important information or assistance to homeopathic physicians. Nevertheless, the Dermatron device was not FDA-approved as a medical device in the United States. In early 1993, Petitioners, having incurred substantial legal costs in fighting the unfounded charges and the prolonged stress of a lagging investigation, agreed to enter into a consent decree, which is directed principally at their future use of electro-dermal screening devices.

The executed consent decree was filed with the United States District Court for the District of Nevada, pursuant to 21 U.S.C. § 301 *et seq.*, and approved on March 23, 1993 (the "Consent Decree"). By its terms, Petitioners agreed not to use any electro-dermal screening devices, including explicitly by name a device called the Life Information System TEN ("LISTEN System"),

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1/ Homeopathy is a medical art practiced throughout the world. It differs markedly from the practice of allopathic medicine in that the emphasis is not (as with Allopathy) on identifying symptoms of patient illnesses and then undertaking to overpower those symptoms with antibiotics and other prescription drugs, or by resort to therapeutic or surgical techniques, but on going beyond the symptom-identification-stage and identifying and treating the actual causes of patient illnesses.

> . . . *unless and until*: (1) there is in effect an approved application for premarket approval (PMA), pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption (IDE), pursuant to 21 U.S.C. § 360j(g), that authorizes the defendants' use of such product(s); and (2) other FDA approval of such products as required by the Act and implementing regulations has been obtained.

See Apdx. G, ¶ 3.A. (Emphasis added). The Consent Decree also provided that, if the FDA made an initial finding that the Petitioners had violated the Consent Decree, a Hearing Officer appointed by the FDA would determine after a hearing whether to uphold the Agency's finding of contempt -- which finding would be subject to judicial review. *Id.* ¶¶ 10-11.

Well in advance of the aforesaid Consent Decree, a separate company, Biosource, Inc., obtained the requisite FDA approval to sponsor use of the LISTEN System device as a research tool under an investigational device exemption ("IDE") pursuant to 21 U.S.C. § 360j(g). As a consequence, Biosource was, and has been up to the present time, cleared by FDA to proceed with its proposed research study with the LISTEN System so long as it satisfied the abbreviated IDE requirements. The clinical investigation Biosource proposed to undertake was described in its Investigational Plan as a study to determine whether conductance readings collected from subjects through use of the LISTEN System can help to identify symptoms associated with a diabetic condition known as diabetes mellitus.[2/]

2/ Integral to the research is, of course, the LISTEN System device. (continued...)

Before start-up of the actual study, Biosource built into its study time-line "the time to train and certify the clinical investigators." In order to become an investigator-participant in the study, each prospective investigator-participant was required to submit to the training/certification process established by Biosource. An important component of the program involved practicing with the LISTEN System "on as many patients as possible" to sharpen skill levels.

On February 25, 1994, during the training/certification process described above, Petitioners received notice from the FDA of a charge of non-compliance with the Consent Decree. Century Clinic had been added in September, 1993, to the list of 32 other potential site "Investigators" selected as "trainee-participants" by Biosource to train on the LISTEN System in preparation for the clinical investigation. Two devices had been placed at the Clinic and a team of four trainee-participants (including Dr. Katrina Tang) had been identified to participate in the training. During the Biosource training and thereafter, the team members received both orally and in writing the same set of instructions from Biosource that was given to all 33 of the trainee-participants, including the instruction to "practice on as many patients as possible" throughout the training period.

Nonetheless, the FDA accused Petitioners in its February 25, 1994 Notice Letter of impermissibly using the LISTEN System device for "diagnostic," not practice, purposes. The claim, more particularly, was that Century Clinic and Dr. Tang used the device "to diagnose diseases and induce patients to submit to further diagnostic tests and treatment." Petitioners

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2/(...continued)
The instrument operates essentially as an ohmmeter, which obtains and records energy flows that pass through a person's body.

disputed the FDA's charge of "diagnostic" use of the LISTEN System, both through sworn testimony and documentary evidence. They made a record that the LISTEN System was instrumental to an FDA-approved diabetes mellitus clinical investigation, that Petitioners' involvement in that investigation as trainees was in every particular in accord with the Investigational Plan and the instructions of the study Sponsor (Biosource), and that at no time did Dr. Tang or anyone else at Century Clinic use the LISTEN System to diagnose patients. Indeed, since commencement of this action over 5 ½ years ago, no electro-dermal device has ever been on the Clinic premises, let alone been used (for any purpose) by Dr. Tang.

The FDA offered in response principally a tape recording of undercover FDA agent Beverly Ritter during her one visit to Century Clinic in February 1994. The tape recording is badly garbled and has numerous unexplained gaps. Even more problematic, it includes only the final portion of agent Ritter's visit with Dr. Tang; the first 30 minutes of her appointment were inexplicably not captured on tape. Moreover, despite Petitioners' request, the FDA refused to permit Ms. Ritter to be examined under oath or subjected to cross-examination at any point after the FDA's charges of contempt were issued.

II. Proceedings Before the Administrative Hearing Officer

On December 11, 1995, the Hearing Officer issued his opinion finding that the Petitioners' "use of the two devices violated the Consent Decree." Apdx. D, at 57a. In reaching this conclusion the Hearing Officer determined the FDA had established that Petitioners used the LISTEN System "for the purpose of determining whether it appeared that patients had serious diseases and conditions, which findings the patients

were told would need to be verified by (expensive) tests." *See id.* at 39a. The Hearing Officer expressly declined to determine which evidentiary standard -- the "clear and convincing" standard applicable to civil contempt actions or the "preponderance of the evidence" standard applicable in other civil proceedings -- governed the Agency's charges that the Petitioners had violated the Consent Decree. *Id.* at 53a-54a. The Hearing Officer only stated, "I do not need to reach the issue of which standard is applicable, given that I find that FDA has proven its charges even under the judicial civil contempt standard of 'clear and convincing' evidence." *Id.* at 54a n.32. Notably, the Hearing Officer defined the "clear and convincing evidence" standard as being met merely if the "facts alleged are 'highly probable.'" *Id.* at 54a.

With respect to the undercover tape recording by FDA agent Ritter, the Hearing Officer acknowledged that the agent failed to record the entire initial portion of her visit to Century Clinic (*see id.* at 39a n.14), and that the tape was "inaudible in sections" (*see id.* at 53a), but viewed these deficiencies as "beside the point." The Hearing Officer also failed to view as significant the fact that FDA agent Ritter failed to give sworn testimony and refused to be cross-examined. *See id.* at 53a n.30. As a consequence of the Hearing Officer's findings, a penalty of $400,000.00 was assessed against Petitioners.[3/]

3/ The Consent Decree calls for a forfeiture of $200,000.00 per device upon finding it was used in violation of the Decree. *See* Apdx. G, ¶ 10. The Hearing Officer doubled the fine because Century Clinic had received two devices from Biosource for purposes of the study.

III. Proceedings in the District Court

The Hearing Officer's decision was appealed to the district court pursuant to paragraph 10 of the Consent Decree. The district court, on the recommendation of a Magistrate Judge, affirmed the Hearing Officer's decision. Apdx. B, at 8a. The Magistrate Judge had expressly determined that the FDA proceeding was "one sounding in civil contempt." *See* Apdx. C, at 20a. Further, the Magistrate Judge, over Petitioners' objection, ruled that the "clear and convincing" standard applicable in civil contempt actions is met if there is "evidence sufficient to reasonably satisfy the fact finder that it is highly probable the ultimate fact at issue happened." *Id.* at 19a (citations omitted). As support for this definition, the Magistrate Judge cited this Court's decision in *Colorado v. New Mexico*, 467 U.S. 310, 315 (1984), and two prior Ninth Circuit cases -- *In re Dual-Deck Video Cassette Recorder Antitrust Litig.*, 10 F.3d 693 (9th Cir. 1993) and *Vertex Distrib., Inc. v. Falcon Foam Plastics, Inc.*, 689 F.2d 885 (9th Cir. 1982). Based on this definition of the evidentiary standard, the district court concluded that there was sufficient record evidence to sustain, as not arbitrary or capricious, the Hearing Officer's ruling. *Id.* at 27a.

IV. Proceedings in the Court of Appeals

Petitioners appealed the entire district court judgment. The court of appeals affirmed in a four-page opinion. *See* Apdx. A. In so doing, the court of appeals did not take issue with and implicitly adopted the district court and Hearing Officer's proffered definition of "clear and convincing" evidence. It furthermore held that, "[e]ven assuming that Biosource could have authorized Defendants to 'practice' on patients, there is substantial evidence in the administrative record to support the Hearing Officer's determination that

Defendants used the LISTEN System for diagnostic purposes beyond what the diabetes study authorized." *Id.* at 3a. The only evidence cited by the court below to support the Hearing Officer's determination that Century Clinic and Dr. Tang had used the LISTEN System for "diagnostic" purposes was the only record evidence available, *i.e.*, portions of the undercover tape recording by FDA agent Ritter. The court of appeals rejected Petitioners' contentions regarding the numerous flaws in, and the inherent unreliability of, the tape recording, addressing only one of Petitioners' several claims about the tape – the fact that the recording was "badly garbled, frequently inaudible, and punctuated by numerous, unexplained gaps of silence." *See id.* at 3a (commenting that "questions dealing with the credibility and the weight of the evidence belong to the Hearing Officer"). Unaddressed by the court below were Petitioners' other claims about the recording, including that it omitted a crucial and material portion of agent Ritter's visit to the Clinic and that the Agency refused to permit Ms. Ritter's cross-examination.

REASONS FOR GRANTING THE WRIT

I. This Court's Review is Necessary to Resolve the Differences Among the Circuits, as Well as Within its Own Decisions, as to the Proof Required to Satisfy the "Clear and Convincing Evidence" Standard

This petition for certiorari should be granted to review the Hearing Officer's finding, as affirmed by the district court and the court of appeals, that the "clear and convincing evidence" standard is satisfied upon a mere showing that the

"facts alleged are 'highly probable.'" Apdx. D, at 54a.[4/] The manner in which the "clear and convincing evidence" standard was defined in this case -- and the way in which it is generally defined in the Ninth Circuit -- is in irreconcilable tension with this Court's most recent definition of the term. It also differs from the definitions articulated by other circuits, which require substantially more than "highly probable" proof to meet the "clear and convincing" evidentiary burden. The "clear and convincing" standard is one that federal courts repeatedly apply in various types of cases (including civil contempt actions like the one here) and is found in numerous laws passed by Congress.[5/] Inconsistent application of the standard directly contravenes principles of uniformity and consistency in the law, and, to the extent tolerated, bears directly on considerations of fundamental fairness and due process. It is therefore imperative that this Court undertake a review of this case to clarify for courts, jurors, and litigants what is meant by "clear and convincing evidence," and establish for all a single standard requiring uniform application.

While there is no dispute among the federal courts that, in civil contempt cases like the one at bar, the plaintiff must prove by "clear and convincing evidence" that the defendant violated a clear and unambiguous order of the court, *see, e.g., Piggly Wiggly Clarksville, Inc. v. Mrs. Baird's Bakeries*, 177

4/ The U.S. Magistrate Judge in this case similarly defined "clear and convincing evidence" as evidence "reasonably satisfy[ing] the fact finder that it is highly probable the ultimate fact at issue happened." Apdx. C, at 19a.

5/ *See, e.g.*, 5 U.S.C. § 1214(b)(4)(B)(ii) (Supp. 1992); 8 U.S.C. § 1154(a)(2)(A)(ii) (1988); 10 U.S.C. § 850a(b) (1988); 15 U.S.C. §§ 6604(a), (b)(3) (1999); 18 U.S.C. § 3148(b)(1)(B) (1988); 26 U.S.C. § 280G(b)(2)(C)(ii) (1988).

F.3d 380, 382 (5th Cir. 1999), there appears to be no judicial consensus as to what "clear and convincing evidence" means. As one lower court recently observed, the definition of the "clear and convincing" standard of proof "has caused considerable consternation among courts and commentators." *Kaszuk v. Bakery & Confectionary Union & Industry Int'l Pension Fund*, 638 F. Supp. 365, 373 (N.D. Ill. 1985). There are, in fact, at least three separate definitions of the standard applied by the federal circuits, with each definition undeniably -- and confusingly -- giving rise to differing burdens requiring uneven quantums of proof.

This Court's most recent pronouncement of the level of proof necessary for a plaintiff to satisfy the "clear and convincing evidence" standard is quite different -- and significantly more rigorous -- than the definition articulated below and applied in this case. In *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261 (1990), the Court defined the "clear and convincing" standard of proof as meaning

> evidence which 'produces in the mind of the trier of fact a firm belief or conviction as to the truth of the allegations sought to be established, evidence so clear, direct and weighty and convincing as to enable [the factfinder] to come to a clear conviction, without hesitancy, of the truth of the precise facts in issue.'

Id. at 285 n.11 (quoting *In re Jobes*, 108 N.J. 394, 407-08, 529 A.2d 434, 441 (N.J. 1987)).[6/]

6/ *Cruzan* involved a guardian's attempt to terminate unwanted medical treatment for a person declared incompetent.

The Fifth Circuit Court of Appeals recently applied this definition when finding for the defendant in a civil contempt proceeding similar to this case. *See Travelhost, Inc. v. Blandford*, 68 F.3d 958, 961 (5th Cir. 1995) (citing *Cruzan*, 497 U.S. at 285 n.11 and *In re Medrano*, 956 F.2d 101, 102 (5th Cir. 1992)). Furthermore, the Third Circuit and lower courts in the Second Circuit have adopted a definition of "clear and convincing evidence" identical to the one set forth by this Court in *Cruzan*. *See, e.g., United States Fire Ins. Co. v. Royal Ins. Co.*, 759 F.2d 306, 309 (3d Cir. 1985) ("'[The witnesses'] testimony [must be] so clear, direct, weighty and convincing as to enable the jury to come to a clear conviction, without hesitancy, of the truth of the precise facts in issue . . . .'") (citation omitted); *Elliott Assocs., L.P. v. Republic of Peru*, 12 F. Supp. 2d 328, 345 (S.D.N.Y. 1998) (quoting *Cruzan*, 497 U.S. at 285 n.11), *rev'd on other grounds*, No. 98-9268, 1999 U.S. App. LEXIS 26370 (2d Cir. Oct. 20, 1999).

The considerably more relaxed definition of "clear and convincing evidence" utilized in this case by the Hearing Officer, and followed by the courts below, was employed by this Court in *Colorado v. New Mexico*, 467 U.S. 310 (1984), a case decided six years *before Cruzan*. The Court there, in the context of an interstate water dispute, noted that "clear and convincing evidence" is evidence that "place[s] in the ultimate factfinder an abiding conviction that the truth of [the plaintiff's] factual contentions are 'highly probable.'" *Id.* at 316 (citing C. McCormick, *Law of Evidence* § 320, at 679 (1954)). This "highly probable" definition continues to be accepted law in the Ninth Circuit, *see, e.g., Lisenbee v. Henry*, 166 F.3d 997, 1000 (9th Cir.), *cert. denied*, 120 S. Ct. 82 (1999), and remains as well the law of the Federal, Eleventh, Sixth, and Tenth Circuits. *See, e.g., Buildex, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988); *United States v. Owens*, 854 F.2d 432, 436 n.8 (11th Cir. 1988); *Disner v. Westinghouse Elec. Corp.*,

726 F.2d 1106, 1111 (6th Cir. 1984); *United States v. Denny-Shaffer*, 2 F.3d 999, 1015-16 (10th Cir. 1993).

Undeniably, the definitions in *Cruzan*, on the one hand, and in *Colorado*, on the other, impose fundamentally different standards of proof on the factfinder. *Cruzan*, by its plain language, requires a higher level of certainty -- i.e., "evidence so clear, direct and weighty and convincing," coupled with a "clear conviction, without hesitancy, of the truth of the precise facts" -- than does the less exacting "probability" standard in *Colorado*. Thus, facts sufficient to satisfy the *Colorado* definition of "clear and convincing evidence" could well fail the more demanding definition set forth in *Cruzan*.

There is yet a third definition of "clear and convincing evidence" that has been accepted in several circuits -- one that is even more demanding than both definitions already discussed. The Eighth, Seventh, and First Circuits have defined "clear and convincing evidence" to mean the type and quantum of "evidence which admits no reasonable doubt." *See, e.g., Eldridge v. Sullivan*, 980 F.2d 499, 500 (8th Cir. 1992) (commenting that some "courts have defined clear, convincing and cogent evidence as, that evidence which admits *no reasonable doubt*" and applying that definition to the facts of the case), citing *Radio Corp. of Am. v. Radio Eng'g Labs., Inc.*, 293 U.S. 1, 7-8 (1934) (emphasis added); *Tatro v. Kervin*, 41 F.3d 9, 15 (1st Cir. 1994) ("'clear and convincing proof' has been described as 'proof beyond a reasonable, i.e., a well-founded doubt'"); *Parker v. Sullivan*, 891 F.2d 185, 188 (7th Cir. 1989) ("[p]roof by clear and convincing evidence has been defined as 'the quantum of proof which leaves no reasonable doubt in the mind of the trier of fact as to the truth of the

proposition in question'") (citation omitted).[7] Likewise, the Third Circuit has defined "clear and convincing evidence" in the context of civil contempt proceedings as being satisfied only if there is no "ground to doubt the wrongfulness of the conduct of the defendant." *See Quinter v. Volkswagen of Am.*, 676 F.2d 969, 974 (3d Cir. 1982) (citing *Fox v. Capitol Co.*, 96 F.2d 684, 686 (3d Cir. 1938)); *also see* note 9 *infra*.[8]

There is thus a pressing need for this Court to grant certiorari in this case and use it as the vehicle for establishing a uniform definition of the "clear and convincing evidence" standard.[9] This Court has recognized the importance of

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7/ The District of Columbia Circuit has recently expressed the standard in similarly rigorous terms, proclaiming that "the clear-and-convincing evidence standard generally requires the trier of fact, in viewing each party's pile of evidence, to reach a *firm conviction of the truth on the evidence about which he or she is certain.*" *Association of Am. Physicians & Surgeons, Inc. v. Clinton*, 187 F.3d 655, 659-60 (D.C. Cir. 1999) (emphasis added); *United States v. Montague*, 40 F.3d 1251, 1254 (D.C. Cir. 1994) (emphasis added).

8/ While this Court's 1979 decision in *Addington v. Texas*, 441 U.S. 418, 432 (1979), suggests that a "no-reasonable-doubt" definition for "clear and convincing evidence" may too closely approximate the standard of proof applicable in criminal cases (i.e., "*beyond* a reasonable doubt") to survive scrutiny, that admonition appears not to have registered on the circuit courts identified above (*see also* note 7).

9/ Adding to the present state of confusion, the definition of "clear and convincing evidence" has varied significantly *within* some of the federal circuits, depending on the panel deciding the case. *Compare, e.g.*, D.C. Circuit: *Clinton*, 187 F.3d at 659-60 (defining "clear and convincing" evidence as "evidence about which he or she is certain") *with Southern Pacific Communications Co. v. AT & T Co.*, 740 F.2d 980, 1004-05 (D.C. Cir. 1984) (defining standard as "highly probably true"), *cert. denied*, 470 U.S. 1005 (1985); Third Circuit: *Quinter*, 676 F.2d at 974 (requiring "no

(continued...)

providing litigants, juries, and courts with clear standards of proof. *See Addington v. Texas*, 441 U.S. 418, 423-25 (1979) ("adopting a 'standard of proof is more than an empty semantic exercise'") (citation omitted). It, furthermore, has cautioned against the proliferation of judicial review standards "without good reason," noting that too many standards "make the law more complicated." *First Options of Chicago, Inc. v. Kaplan*, 514 U.S. 938, 948 (1995). Resolving the increasing tension within this Court's own precedents, as well as settling existing differences among the circuits as to the accepted definition of "clear and convincing evidence," furthers these principles.

The present case is particularly well suited to that purpose. While we firmly believe there should be no finding of contempt in this case under *any* of the mentioned evidentiary standards (*see* discussion *infra* at Part II), the Hearing Officer undeniably would have been required to rule in Petitioners' favor had he applied either the more exacting definition of "clear and convincing evidence" adopted in *Cruzan*, or the even more rigorous "no-reasonable-doubt" definition accepted by the Eighth, Seventh, and First Circuits. Because contempt is a weighty penalty which should not be casually imposed, *see City*

9/(...continued)
ground to doubt" to meet "clear and convincing evidence" standard) *with United States Fire Ins.*, 759 F.2d at 309 (applying same standard set forth in *Cruzan*); Eighth Circuit: *Eldridge*, 980 F.2d at 500 (requiring "evidence which admits no reasonable doubt" to meet standard) *with United States v. Crow*, 37 F.3d 1319, 1323 (8th Cir. 1994) (applying "highly probable" definition); Fifth Circuit: *Travelhost*, 68 F.3d at 961 (applying *Cruzan* definition) *with United States v. Dixon*, 185 F.3d 393, 404 (5th Cir. 1999) (applying "highly probable" definition). Indeed, the Fifth Circuit in *Dixon* attempted to reconcile two of the different definitions by suggesting that the "'clear conviction' language can be seen as another version of [the] 'highly probable' articulation of the clear and convincing standard." *Id.* at 404 n.11. Clarification from this Court is thus critically important.

of New York v. Local 28, Sheet Metal Workers' Int'l Ass'n, 170 F.3d 279, 283 (2d Cir. 1999), this Court should review this case and overturn the decision of the court of appeals, assigning error to the "highly probable" definition of "clear and convincing evidence" adopted below.

II. The Court of Appeals Erred as a Matter of Law by Affirming an Administrative Finding of Contempt Based Exclusively on an Incomplete and Defective Tape Recording Created by an Agency Official Whom Petitioners Could Not Cross-Examine

This case also merits Supreme Court review because it raises the important question of whether an administrative Agency can find a defendant in contempt of a federal court order where the *only* identified and identifiable record evidence of misconduct is an uncorroborated, unauthenticated, incomplete, and frequently unintelligible recording, clandestinely taped (without Petitioners' knowledge or consent) by an undercover Agency official who refuses to submit to cross-examination. The court of appeals' affirmance of the Hearing Officer's finding of contempt was based exclusively on the tape recording created by undercover FDA agent Beverly Ritter. Unheeded were Petitioners' objections that the tape recording was defective as an evidentiary matter for a host of reasons, including its garbled state, unexplained gaps of silence, and the inexplicable failure to record crucial dialogue between agent Ritter and Dr. Tang.[10/] The court of appeals also regarded

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10/ Federal officials are routinely required by law to immediately seal undercover recordings of conversations obtained in a manner similar to the recording here in order to insure their accuracy and authenticity. *See* 18 U.S.C. § 2518(8)(a) (1988). To the extent that the procedure is not followed, or occurs only after some delay, this Court has made it clear that

(continued...)

as unimportant the fact that Petitioners had requested but been denied the opportunity to cross-examine agent Ritter -- the person who alone decided when, where, and under what circumstances to activate the tape recording.

a. This Court has not hesitated to exercise its jurisdiction to set aside administrative decisions that are based on evidence that is of questionable reliability, *see, e.g., Gastelum-Quinones v. Kennedy*, 374 U.S. 469 (1963); *Bridges v. Wixon*, 326 U.S. 135 (1945), or that has not been subject to cross-examination or testing by the party against whom it is used. *See, e.g., Greene v. McElroy*, 360 U.S. 474 (1959). That is an apt description of the evidence on which the contempt findings here are based. The only evidence cited by the Hearing Officer, the district court, and the court of appeals to support the conclusion that the Petitioners had used the LISTEN System for "diagnostic" purposes were portions of the Ritter tape recording. Apdx. A, at 3a-4a. That recording, according to the court below, showed that Dr. Tang told agent Ritter the LISTEN System "told me you [have] been exposed to a little copper and aluminum." *Id.* at 3a. Coupling that statement with the later recorded statement by Dr. Tang's assistant "about further testing the doctor needs you to go through," including a test that "would tell us the degree of aluminum in your system," formed the evidentiary basis for a finding of civil contempt for

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10/(...continued)
the integrity of the recording has been placed in sufficient doubt to preclude the federal government from using the tape as evidence or relying on it to support a charge of misconduct. *See, e.g., United States v. Ojeda Rios*, 495 U.S. 257, 264 (1990); *and see United States v. Gigante*, 538 F.2d 502, 506-07 (2d Cir. 1976). At no time has the FDA shown that the Ritter tape was satisfactorily protected so as to entitle it to a presumption of authenticity or reliability for present purposes.

which the Petitioners were ordered to pay the astronomical fine of $400,000.00. *Id.* at 3a-4a.

Because the Ritter tape was badly compromised, it never should have been available to the Hearing Officer or the courts. Particularly disturbing in this regard was the tape's incompleteness -- only a portion of agent Ritter's visit to the Century Clinic was recorded. Not captured on tape were the critically important first 30 minutes of agent Ritter's examination by Dr. Tang. Yet, it was during this initial phase of the patient visit that Dr. Tang as was her regular custom and practice, in fact performed her *only* "diagnosis" of agent Ritter. Because agent Ritter elected not to turn her recorder on until much later -- with full knowledge that Dr. Tang's diagnosis had already taken place -- the portion of the dialogue taped was wholly devoid of context and should not have been accepted into evidence. *See United States v. Slade*, 627 F.2d 293, 301 (D.C. Cir.) (if tape is not trustworthy, it cannot be considered), *cert. denied*, 449 U.S. 1034 (1980); *Stringel v. Methodist Hosp. of Indiana*, 89 F.3d 415, 422 (7th Cir. 1996) (indicating a "miscarriage of justice" could occur if "the tape recorder failed to pick up some crucial portion of the dialogue"); *and see Spurlock v. Department of Justice*, 894 F.2d 1328, 1330 (Fed. Cir. 1990) (reversing administrative decision and holding that "omissions in a purportedly complete account, imprecision, and errors detract from the weight to be accorded the evidence upon which an administrative board bases it decision"); *ABC Air Freight Co. v. Civil Aeronautics Bd.*, 391 F.2d 295, 305 (2d Cir. 1968) ("It is exceedingly dangerous business -- indeed under some circumstances a denial of the fair hearing required by the APA -- for an agency to seize upon a single exhibit in a

large record . . . and make this an important basis for decision without benefit of cross-examination . . . .").[11/]

The argument that cross-examination of the recording witness was Petitioners' means for attacking the incompleteness of the Ritter tape recording, *see Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596 (1993) (noting that vigorous cross-examination is traditional means of attacking shaky evidence), is not available in this case. The FDA refused Petitioners' demands for an opportunity to cross-examine agent Ritter.[12/] This Court has "frequently emphasized that the right to confront and cross-examine witnesses is a fundamental aspect of procedural due process." *See Jenkins v. McKeithen*,

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11/ In addition to the uncontroverted fact that the Ritter tape omitted critically material parts of agent Ritter's visit to the Clinic, the tape also should not have been considered below because it was fundamentally flawed in other critical respects. Thus, the Ritter tape was never authenticated by the FDA, *see Stringel v. Methodist Hosp. of Indiana*, 89 F.3d 415, 419 (7th Cir. 1996) (to be considered "'the government must prove, by clear and convincing evidence, that the tape is a true, accurate, and authentic recording of the conversation, at a given time, between the parties involved'") (citations omitted). The Ritter tape was, moreover, frequently inaudible and unintelligible, *see Vukadinovich v. Zentz*, 995 F.2d 750, 753 (7th Cir. 1993) (excluding tape recording that was "partially inaudible"); *Stringel*, 89 F.3d at 419 ("We have also emphasized the [decision maker's] obligation to ascertain that the recording itself is sufficiently audible to constitute reliable evidence of the conversation recorded") (citation omitted). And the Ritter tape was frequently interrupted with unexplained gaps of silence.

12/ Indeed, Petitioners sought also to take the depositions of the other members of the FDA "investigative" team in order to interrogate them on the largely hearsay discussion relied upon in the FDA notice letter and charging memoranda. These documents were the only support offered by the FDA other than agent Ritter's recording and the chronicle of her visit to the Clinic. The FDA also denied Petitioners the opportunity to depose these FDA employees.

395 U.S. 411, 428 (1969) (citation omitted). Indeed, this Court has been "zealous to protect" a party's right to cross-examine his accuser "not only in criminal cases . . . but also in all types of cases where *administrative* and regulatory actions [are] under scrutiny." *Greene*, 360 U.S. at 496-97 (citations omitted; emphasis added).

Nor does the fact that the Petitioners were charged with civil, and not criminal, contempt in any way vitiate their right to cross-examine agent Ritter. *See, e.g., Consolidation Coal Co. v. United Mine Workers*, 514 F.2d 763, 765 (6th Cir. 1975) ("'Like any civil litigant, a civil contemnor [sic] is . . . clearly entitled to those due process rights, applicable to every judicial proceeding. . . .'").[13/] Accordingly, Respondent's refusal to permit agent Ritter to be deposed and cross-examined provides yet another ground to exclude her incomplete and otherwise substandard tape recording. *See Hines v. Brandon Steel Decks, Inc.*, 886 F.2d 299, 303 (11th Cir.1989) ("the inability to cross-examine the investigator" indicates a lack of "trustworthiness of a public report"); *Wilson v. Attaway*, 757 F.2d 1227, 1245 (11th Cir. 1985) (report by government agent excluded in part because proponent "failed to afford the possibility of cross-examination").

13/ The Consent Decree certainly does not strip Petitioners of their ability to cross-examine agent Ritter. Paragraph 10 of the Consent Decree stated that the Petitioners' "shall have a *full opportunity* to submit written materials on their behalf, and to make an oral presentation to the FDA." Apdx. G, ¶ 10 (emphasis added). Nowhere does the Consent Decree even suggest, much less explicitly state, that Petitioners waived their right to prepare a defense through cross-examination of Agency witnesses who submit materials on behalf of the FDA. *See D.H. Overmyer Co. v. Frick Co.*, 405 U.S. 174 (1972) (waiver of procedural due process rights must be clear, knowing and voluntary).

b. Furthermore, in situations similar to the one at hand -- where the government's case is based solely on the recorded statements of the defendant -- courts have required independent corroborating evidence to support the government's charges. *See, e.g., United States v. Marshall*, 863 F.2d 1285, 1287-88 (6th Cir. 1988) (reversing conviction against defendant where the only evidence offered by the government was the defendant's statements recorded by an undercover agent, which statements were never corroborated by independent evidence); *United States v. Trombley*, 733 F.2d 35, 36-37 (6th Cir. 1984) (same). While the cases cited above arose in the criminal context, they should apply with equal force to the present contempt action, in which the government seeks to impose a weighty $400,000.00 fine as punishment. Indeed, the "independent corroborating evidence" rule would appear to have unmistakable application under the *Cruzan* "clear and convincing evidence" standard.

Yet, there was no corroborating evidence presented by the FDA in this case. To be sure, there is a considerable amount of evidence in the administrative record other than the Ritter tape, but *none* supports a finding that Dr. Tang used the LISTEN System for "diagnostic" purposes. To the contrary, the evidence is overwhelming that Petitioners used the LISTEN System only "for practice" in accordance with the instructions of the study Sponsor Biosource. Indeed, the Sponsor testified --without contradiction -- that the LISTEN System could not have been used diagnostically by Dr. Tang even if she had wanted to (which, she testified, she did not). There was, moreover, uncontradicted testimony under oath from both Dr. Tang and Dr. Keith Carlson, a second fully licensed M.D. and H.M.D. at the Clinic who attended the entire Ritter visit with Dr. Tang; both flatly denied any "diagnostic" use of the LISTEN System. Their *undisputed testimony* is that the diagnosis of agent Ritter occurred well before the practice

session on the LISTEN System started, during the initial *unrecorded* half-hour consultation and examination of the patient. Both attending physicians are emphatic on the point that Dr. Tang promptly wrote her diagnosis in agent Ritter's medical chart -- and the medical chart itself so reflects.

The court of appeals disregarded entirely the aforesaid *undisputed sworn testimony*, as confirmed by agent Ritter's medical chart. It chose *not* to "canvas the whole record" -- "taking into account contradictory evidence or evidence from which conflicting inferences could be drawn" -- as this Court directed in *Universal Camera Corp. v. National Labor Relations Bd.*, 340 U.S. 474, 488 (1951).[14/] Rather, because follow-up tests were recommended to agent Ritter by Dr. Tang's assistant after the session on the LISTEN device had concluded (*see* Apdx. A, at 3a-4a), which tests according to the court of appeals, "corresponded closely to the very conditions allegedly identified by the LISTEN System" *(id.)*, Petitioners were held in contempt.

Yet, abundant record evidence ignored by the Hearing Officer and the courts below makes clear that all of the "testing" recommended by Dr. Tang's assistant had been identified in writing on agent Ritter's medical chart *during the initial physical examination* that had not been tape recorded by agent Ritter. This was specifically brought to the appellate court's attention on Petitioner's rehearing petition -- on the assumption that said "shorthand" chart entries must either have been missed by the court of appeals, or not fully understood and

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14/ This requirement to "canvas the whole record" and consider conflicting evidence is especially appropriate in civil contempt cases "because of the formidable and potentially harmful nature of the contempt power." *See, e.g., Local 28,* 170 F.3d at 283 (noting that in contempt cases, the court appeals' review "is more rigorous than in other contexts").

appreciated. *See* Apdx. A, at 4a. Those handwritten, shorthand entries not only confirm the testimony of *all* the witnesses, to the undisputed effect that Dr. Tang made her diagnosis of agent Ritter during the initial patient examination (well before the LISTEN System was used), but they also show that Dr. Tang also wrote down her recommended blood tests for the patient *at the same time*. Notably, the nurse who is heard on tape advising agent Ritter on the recommended further tests had only agent Ritter's medical charts. She had not been present for the later LISTEN System practice session and had not been advised by anyone of what occurred during that session. The court of appeals nonetheless continued to ignore this record evidence and denied the rehearing petition. *See* Apdx. E.

This case thus cries out for Supreme Court review. It is the worst example of an agency review process misusing both the standard of proof and the rules of evidence to "legitimize" a manipulated result sloppily and unjustly contrived by Agency "investigators," with the all too convenient "rubber stamp" affirmance by the courts below on a backhanded "not arbitrary or capricious" basis. The fact is that, in light of the FDA's charge of contempt, it was incumbent on the Agency to scrutinize the "diagnosis" allegations of its "investigative team" (admittedly devoid of medical knowledge or expertise) under the more exacting "clear and convincing evidence" standard. This it did not do, contrary to this Court's definition of the standard in *Cruzan*.

Reliance on an incomplete tape recording, of admittedly poor quality, to the exclusion of all else would unquestionably have not passed muster in those Circuits which regard the more demanding "clear and convincing evidence" standard to be the law. It should not be that federal courts and federal agencies can arrive at so dramatically different results because of differences in the quantum of proof required under what

purports to be the same evidentiary standard. Fundamental fairness demands that this Court grant the instant petition to resolve the inconsistency in the Circuits.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Dated: December 13, 1999 Respectfully submitted,

Wm. Bradford Reynolds
(Counsel of Record)
Stephen Weissman
Collier, Shannon, Rill
& Scott, PPLC
3050 K Street, N.W., Suite 400
Washington, D.C. 20007
(202) 342-8400

Thomas C. Bradley
Sinai, Schroeder, Mooney,
Boetsch & Bradley
448 Hill Street
Reno, NV 89501
(702) 323-5178

Attorneys for Petitioners

APPENDICES

APPENDIX A

NOT FOR PUBLICATION
United States Court of Appeals for the Ninth Circuit

No. 98-16373
D.C. No. CV-N-93-194-ECR (RAM)

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

CENTURY CLINIC, INC., a corporation,
and KATRINA TANG, H.M.D., an individual,
Defendants-Appellants,

and

YTWEN TANG, M.D., an individual,
Defendant.

Appeal from the United States District Court
for the District of Nevada
Edward C. Reed, Jr., District Judge, Presiding

Argued and Submitted June 14, 1999
San Francisco, California
Filed July 22, 1999

MEMORANDUM[1]

Before: T.G. NELSON, HAWKINS and GRABER, Circuit Judges.

[1] This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as may be provided by 9th Cir. R. 36-3.

Defendants appeal from the district court's decision affirming the determination by an administrative law judge (ALJ) that Defendants had misused an investigational medical device, the LISTEN System, in violation of a consent decree entered into with Plaintiff. In this timely appeal, Defendants claim that the ALJ's ruling lacks factual and legal support. We affirm.

Plaintiff first argues that this court lacks jurisdiction to review the district court's judgment on the merits, because Defendants failed to designate that judgment in their notice of appeal as the "judgment . . . appealed from" under Federal Rule of Appellate Procedure 3(c). This court has held that a party's "failure to designate the specific order appealed from does not preclude this court's review of the issues presented by that order." *United States v. $84,740.00 Currency*, 981 F.2d 1110, 1112 (9th Cir. 1992). In deciding whether such review is warranted, we have looked to "(1) whether the [appellees] had notice of the issue on appeal; and, (2) whether they had an opportunity to fully brief the issue." *Id.*

Here, Plaintiff had notice of Defendants' intent to challenge the district court's judgment on the merits, because Defendants devoted their entire opening brief to challenging the factual and legal basis of the ALJ's ruling. Moreover, Plaintiff cannot claim prejudice as a result of a decision to review the judgment on the merits, because Plaintiff had a full opportunity to brief the issues related to that decision. *See id.* (holding the same in similar circumstances). Therefore, we have jurisdiction to review the district court's judgment on the merits.

Defendants make two basic arguments to support their claim that the ALJ's ruling lacked a factual basis and was legally unsound. First, Defendants contend that their actions did not violate the consent decree, because the sponsor of a

diabetes study in which Defendants were participating, Biosource, authorized them to "practice" on patients with the LISTEN System without maintaining records of its use. Second, Defendants challenge the evidentiary basis of the ALJ's determination that Defendants impermissibly had used the LISTEN System for diagnostic purposes, arguing that the tape recording of Dr. Tang's examination of the undercover agent was unreliable and that Dr. Tang diagnosed the agent before using the LISTEN System device.

Even assuming that Biosource could have authorized Defendants to "practice" on patients, there is substantial evidence in the administrative record to support the ALJ's determination that Defendants used the LISTEN System for diagnostic purposes beyond what the diabetes study authorized. For example, Dr . Tang told the agent that the LISTEN System "told me you [have] been exposed to a little copper and aluminum." Immediately following the examination, Dr. Tang's assistant talked to the agent "about further testing the doctor needs you to go through," including a blood test that "would tell us the degree of aluminum in your system." On the basis of such evidence, it was reasonable for the ALJ to infer that Dr. Tang had used the LISTEN System for diagnostic purposes.

Defendants argue that this court should give no credence to the tape recording, because it was "badly garbled, frequently inaudible, and punctuated by numerous, unexplained gaps of silence." However, questions dealing with the credibility and the weight of the evidence belong to the ALJ. *See Todd Pac. Shipyards Corp. v. Director, OWCP*, 914 F.2d 1317, 1321 (9th Cir. 1990) (stating that it is within the ALJ's discretion to determine the credibility of witnesses). Here, the ALJ did not see fit to discount the evidentiary value of the tape recording, and there is nothing in the record to suggest that the ALJ's weighing of the evidence was erroneous.

Furthermore, Defendants contend that the record establishes that Dr. Tang formulated her diagnosis of the agent before using the LISTEN System and thus could not have used the device for a diagnostic purpose. Defendants' version of events cannot be squared with the record. The tests recommended by Dr. Tang sought to do more than verify her initial diagnosis. Indeed, those tests corresponded closely to the very conditions allegedly identified by the LISTEN System. For instance, Dr. Tang used the LISTEN System to "check" for herpes and hepatitis. Then, after the examination, Dr. Tang's assistant told the agent that a blood test was necessary to confirm whether she had either of those diseases. Nowhere in the agent's medical record is there any reference to herpes or hepatitis. Dr. Tang's diagnosis could have arisen only as a result of her use of the LISTEN System. On the basis of such evidence, it was reasonable for the ALJ to conclude that Defendants had used the LISTEN System for diagnostic purposes, in violation of the consent decree.

AFFIRMED.

APPENDIX B

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

CASE NUMBER: CV-N-93-194-ECR (RAM)

UNITED STATES OF AMERICA,

Plaintiff,

v.

CENTURY CLINIC, INC. *et al.*,

Defendants.

FILED MAR 23 1998
ENTERED & SERVED MAR 23 1998

JUDGMENT IN A CIVIL CASE

____ **Jury Verdict**. This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered it's verdict.

____ **Decision by Court**. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

__xx__ **Decision by Court.** This action came to be considered before the Court. The issues have been considered and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that judgment is entered in favor of plaintiff, United States of America, and against all defendants in the amount of $400,000.

March 23, 1998
Date

LANCE S. WILSON
Clerk

/s/ Marti Campbell
(By) Deputy Clerk

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA
RENO, NEVADA

CV-N-93-194-ECR (RAM)

UNITED STATES OF AMERICA,

Plaintiff,

v.

CENTURY CLINIC, INC. *et al.*,

Defendants.

DATE: March 23, 1998

MINUTES OF THE COURT

PRESENT: EDWARD C. REED, JR. U.S. District Judge

Deputy Clerk:	MARTI CAMPBELL
Reporter:	NONE APPEARING
Counsel for Plaintiff(s):	NONE APPEARING
Counsel for Defendant(s):	NONE APPEARING

MINUTE ORDER IN CHAMBERS

IT IS HEREBY ORDERED that Defendants' Objection (#33), filed on March 6, 1998, to the Magistrate Judge's Report and Recommendation (#31), entered on February 4, 1998, is ***OVERRULED*** and said Report and Recommendation is ***AFFIRMED*** and ***ADOPTED***.

IT IS FURTHER ORDERED that Defendants' petition (#4) for review of final agency action is ***DENIED***.

IT IS FURTHER ORDERED that Defendants' request (#24) for oral argument is ***DENIED***.

IT IS FURTHER ORDERED that the Clerk shall enter judgment in favor of Plaintiff United States of America and against all Defendants in the sum of $400,000.

Defendants Century Clinic and Dr. Katrina Tang entered into a consent decree with the Food and Drug Administration ("FDA") in 1993, in which they agreed not to use the "LISTEN System" acupuncture screening device except for investigational purposes–i.e., for testing the device's efficacy–pursuant to an "investigational device exemption" ("IDE"). Admin. Record, Vol. VII, Ex. J. p. 2. The LISTEN System is apparently simply a ohmmeter: it measures electrical resistance, relative to some reference value, at various points on the human body, in aid of an acupuncturist's or homeopathic physician's diagnosis. It is undisputed that Defendants received approval to so use a LISTEN device pursuant to another firm's IDE. In 1994, however, the FDA sent an undercover investigator to the Century Clinic to determine whether Defendants were in compliance with the consent decree.

The Magistrate Judge carefully considered all arguments raised by Defendants, and correctly concluded that the investigator's report shows a use of the LISTEN System in a manner not permitted by the IDE protocol, and therefore not permitted by the consent decree. For example, Dr. Tang used the LISTEN device to diagnose an exposure to certain metals: "this indicator even told me you have been exposed to a little copper and aluminum." Admin. Record Vol. VIII, Ex. DD, p. 24. A few minutes later an employee of the Century Clinic (later identified as one Rosario Quintana) conferred with the investigator about the need for numerous expensive follow-up tests for, among other things, determining the level of aluminum in the investigator's body. *Id.* at p. 28.

This is merely one example of Defendants' use of the LISTEN device in a manner not permitted by the consent

decree, specifically, diagnostically rather than investigationally. Defendants nonetheless raise a number of arguments, none of which help them. They argue that the LISTEN System was not actually "used," since it was eventually determined that the system did not work at all; this is immaterial, however, since Dr. Tang *purported* to use it, and it would make little sense to disallow actual use while allowing fraudulent or improper use of a proscribed medical device. Defendants further assert that the investigator's report is unreliable, unauthenticated hearsay; the Federal Rules of Evidence generally do not apply to administrative proceedings, however, as the United States correctly notes. Opp'n Br. at 39-40 (#20), and cases cited therein. Defendants present other arguments, but they are irrelevant to the question presented.

In short, the Magistrate Judge correctly concluded that the FDA Hearing Officer's finding of contempt was not arbitrary, capricious, contrary to law, or unsupported by substantial evidence. Defendants do not dispute the rather hefty size of the $400,000 civil contempt fine. Finally, oral argument would clearly not be helpful.

LANCE S. WILSON, CLERK

By /s/ Marti Campbell
Deputy Clerk

APPENDIX C

UNITED STATES DISTRICT OF NEVADA

DISTRICT OF NEVADA

CV-N-93-194-ECR (RAM)

UNITED STATES OF AMERICA,
Plaintiff/Respondent,

vs.

CENTURY CLINIC, INC., *et al.*,
Defendants/Petitioners.

FILED FEB 4 1998

REPORT & RECOMMENDATION
U.S. MAGISTRATE JUDGE

This Report and Recommendation is made to the Honorable Edward C. Reed, Jr., United States District Judge. This action was referred to the undersigned Magistrate Judge pursuant to 28 U.S.C. §636(b)(1)(B) and the Local Rules of Practice, LR IB 1-4.

This matter is before the court on Petitioners' appeal, made pursuant to 42 U.S.C. § 405(g), for judicial review of the final administrative decision of the United States Food and Drug Administration ("FDA"). The decision found Petitioners in contempt of a March 23, 1993, Consent Decree entered by this court, and assessed monetary penalties in the amount of four hundred thousand dollars ($400,000.00) (Doc. #13). Respondent has submitted an opposition to Petitioners' appeal (Doc. #20), and Petitioners have replied (Doc. #23).

I. *BACKGROUND*

On March 23, 1993, Petitioners entered into a Consent Decree of Permanent Injunction ("Consent Decree") with the FDA, whereby the parties stipulated to certain matters relating to the use of various medical screening devices and agreed to monetary disciplinary sanctions for any violations of said decree. The Consent Decree provides that if the FDA discovers Petitioners have violated its terms, Petitioners will be required to forfeit two hundred thousand dollars ($200,000.00), per violation to the FDA, after written notice of said violations and an opportunity by Petitioners to challenge that finding. The decree further establishes procedures for the resolution of any dispute regarding compliance with the decree. This procedure is triggered by the FDA finding Century Clinic has violated the decree. Once a violation is charged, Century Clinic may challenge that finding by submitting written materials and making an oral presentation before an FDA Hearing Officer ("ALJ"). If the decision of the FDA is affirmed by the ALJ, that determination may be further challenged in the District Court, through complete review of the administrative record under the arbitrary and capricious standard.

1. *Consent Decree*

The Consent Decree was entered into on March 23, 1993. Parties to the decree are Century Clinic, Katrina Tang, M.D., H.M.D., ("Dr. Tang") and Tiwen Tang, M.D.[1], both employees of the Clinic, and the United States Department of Justice. The decree was signed in an attempt to resolve problems resulting from criminal allegations and subsequent investigations

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[1] Tiwen Tang is no longer practicing medicine or affiliated with the operations of Century Clinic. Further, although he was a party to the Consent Decree, he is not a party to this action.

directed at Petitioners' use of an electro-acupuncture device, known as the EAV Dermatron. The EAV Dermatron is a medical device, an ohmmeter, used to detect abnormal energy patterns in the human body. The FDA alleged that Petitioners were using the EAV Dermatron to fraudulently diagnose patients with various diseases, such as the Bubonic plague, "exposure to hepatitis," "Epstein Barr Syndrome," and "Nevada underground radiation." (Doc. #20 at 1). The FDA further alleged that Petitioners would recommend that patients undergo expensive tests and treatments pursuant to such diagnosis'. (*Id.*).

The relevant provisions of the Consent Decree prohibit Petitioners from using electro-acupuncture screening devices, such as the EAV Dermatron and including specifically by name the LISTEN System device,

> "unless and until: (1) there is in effect an approved application for premarket approval (PMA), pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption (IDE), pursuant to 21 U.S.C. § 360j(g), that authorizes the defendants' use of such product(s); and (2) other FDA approval of such products as required by the Act and implementing regulations has been obtained." (Consent Decree, Adm. R. Vol. VII Ex. J. at p.2).

An IDE permits an untested and unapproved device to be utilized for investigational purposes only. FDA regulations require that the investigational study be implemented specifically as described in an FDA approved application or pursuant to an Investigational Relations Board ("IRB") approval that strictly follows IDE regulations. (*See* 21 C.F.R. Part 812). The purpose of an IDE is to protect the health and safety of human subjects exposed to unapproved medical

devices. The IDE application calls for thorough and detailed information regarding the proposed investigatory study. The application process aids the FDA in ensuring that safety standards are maintained without unduly hampering the discovery and development of useful medical devices. If a device is used in any manner not specifically documented in the IDE, the device is not used with FDA approval. Because of the health risks involved in testing unapproved devices, FDA's regulations are explicit and approved testing, pursuant to an IDE, is monitored carefully. (*See* 21 C.F.R. § 812.46).

2. *Biosource, Inc.*

On August 6, 1993, Biosource Inc., ("Biosource") a private medical research company, filed an application for an IDE, pursuant to 21 U.S.C. § 360j(g). In the application, Biosource proposed to study a Life Information System Ten device, a machine used for electro-dermal screening. This device is commonly known as the LISTEN System device and is used for the limited purpose of detecting diabetes. The LISTEN System device operates in essentially the same manner as the EAV Dermatron, the device that prompted the consent decree. Both devices are used to detect and record energy imbalances by testing various conductance points associated with specific organs or systems in the human body. The major difference between the devices is that the LISTEN System is hooked up to a computer and the EAV Dermatron to a dial.

On September 10, 1993, the FDA conditionally approved Biosource's IDE application. The purpose of the Biosource study was to determine if the data collected from the LISTEN System device could differentiate persons with insulin dependent diabetes from persons having normal glucose levels without insulin. (Investigational Plan, Adm. R. Vol. VII Ex. M. at 1). Specifically, the conditionally approved IDE stated that the study would require use of the LISTEN System device to

collect data only. (*Id.* at 33). The test on diabetes was then to be done by comparing the data collected by the LISTEN System to data from a blood test that measured glucose levels. In October 1993, Petitioners were chosen to participate in the Biosource study as clinical investigators. To prepare for the study, Petitioners purchased two LISTEN System devices and began the training process, prescribed by Biosource, which encouraged clinical investigators to practice on "as many patients as possible." Petitioners contend they did this without recording or gathering any patient data at the instruction of Biosource, in order to gain familiarity with and accuracy on the device. The FDA contends that instead of using the LISTEN System device for the diabetes mellitus study, for which it was approved, Petitioners used the device in the same manner as they used the EAV Dermatron, i.e. to diagnose patients with various diseases and then to recommend expensive follow up tests and treatments. The FDA concluded that this was an unauthorized use of the device and, therefore, Petitioners were in violation of the Consent Decree.

3. *FDA Notification of Non-Compliance*

On February 25, 1994, the FDA notified Century Clinic, Inc., by way of a letter of non-compliance, that Petitioners Century Clinic Inc., Katrina Tang, M.D., H.M.D., and employees Rosario Quintana and Herbert Ellingwood, Esq., had violated the Consent Decree by using two LISTEN System devices outside of the study permitted under the Biosource IDE and were required to forfeit two hundred thousand dollars ($200,000.00) per violation.[2] Specifically the FDA cited Petitioners for using the LISTEN System to diagnose serious medical diseases, and for failing to follow the guidelines of a

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[2] Use of each device constitutes one violation. Because the FDA found that two devices were being used without authorization, two violations were cited and monetary penalties assessed accordingly.

clinical investigator as per the approved Biosource IDE. They contend Petitioners did not gather screening data called for by the IDE, or the blood glucose levels to be compared to that data. Further, they contend Petitioners used the LISTEN System device without following IDE protocol or FDA regulations and without keeping records required of an investigator under those regulations. The FDA's findings and conclusions were based on two investigations conducted in February of 1994. The first investigation included an undercover operation, wherein an FDA investigator, Beverley Ritter, posed as a patient and was tested with the LISTEN System device. Investigator Ritter reported that during or immediately following her exposure to the LISTEN System device, Dr. Tang informed her that the device indicated abnormalities with her lymphatic, nervous and circulatory systems, that she was hypoglycemic, had the Epstein Barr virus, had been exposed to aluminum, and did not have any strain of HIV. (Undercover Investigation Transcript, Adm. R. Vol. VIII Ex. DD at 13-24). Dr. Tang further informed Investigator Ritter that the device could detect cancer, infections and inflammations. (*Id.* at 7). During the testing, Dr. Tang placed ampules labeled with names of different viruses, as well as various chemicals, pesticides and vaccines onto a circular metal plate in an attempt to "normalize" the readings of the LISTEN System device. (*Id.* at 14-20). After the testing was complete, Dr. Tang recommended that Investigator Ritter undergo a number of subsequent tests and procedures, including but not limited to a costly blood test for aluminum. (*Id.* at 28). This investigation led the FDA to conclude that Dr. Tang was in violation of the Consent Decree, and also led to a subsequent investigation.

On February 10-11, 1994, the FDA inspected Century Clinic once again. The FDA found that although engaged in the Biosource study, Century Clinic was not collecting any data

from patients exposed to the LISTEN System device. (February 1994 Inspection Memorandum, Adm. R. Vol. VIII Ex. HH at 3). Further the investigators interviewed six employees who offered conflicting testimony when questioned about the manner in which the device was used. (*Id.* at 5-10). Dr. Katrina Tang stated at first that she used the device "sometimes." She later changed her testimony to state that she didn't use it. (*Id.* at 5). Mr. Ellingwood, manager of Century Clinic, stated that the device was used on nearly every patient. (*Id.*). However, in his subsequent deposition this statement was denied. (Deposition of Herbert Ellingwood, Esq., Adm. R. Vol. II Ex. B at 45,108). Ms. Rosario Quintana stated that the device was only used if patients were curious about it, and only one or two new patients were tested in the three months preceding the investigation, the last being two weeks prior to the investigation. (February 1994 Inspection Memorandum, Adm. R. Vol. VIII Ex. HH at 7). Ms. Quintana made this statement although she was present two days earlier when Investigator Ritter was examined with the device. Finally, Ms. Teresita O'Gorman told investigators that ten to twenty of every one hundred new patients was tested with the device. (*Id.* at 10). She further testified that she only used the device occasionally on a patient. Mr. Ellingwood testified that Ms. O'Gorman probably used the device more than anyone else at the clinic. The FDA contends that there were five investigators present during the investigation of Century Clinic, all of whom were present during the interviews of the above-named employees. Based on the results of their inspection, the FDA concluded that Century Clinic had in fact violated the Consent Decree.

Petitioners immediately challenged the FDA's findings by following the procedures set forth in the consent decree for administrative review. They claimed that they used the LISTEN System device in accordance with Biosource's IDE. Further, they claimed they did not need to follow IDE protocol or

maintain records of patients exposed to the device because they were merely in the training phase, and just practicing on patients. After reviewing the evidence presented by both parties, the ALJ affirmed the findings and conclusions of the FDA and adopted its recommendation to impose four hundred thousand dollars ($400,000.00) in fines for two cited violations of the Consent Decree. Petitioners subsequently instituted this action.

II. *DISCUSSION*

A. *Standard of Review*

Review of agency determinations is limited to whether the agency's action was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law, or if it was taken without observance of procedure required by law. 5 U.S.C. § 706(2)(A); *Loomis Cabinet Co. v. OSHRC,* 20 F.3d 938, 941 (9th Cir. 1994) (applying standard). Under the arbitrary and capricious standard, the court considers only whether the agency's decision is based on a reasoned evaluation of the relevant factors. *Bicycle Trails Council v. Babbitt,* 82 F.3d 1445, 1466 (9th Cir. 1996); *California Trout v. Schaefer,* 58 F.3d 469, 473 (9th Cir. 1995). The court may reverse only where the agency has relied on factors that Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or it is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. *Western Radio Servs. Co. v. Espy,* 79 F.3d 896, 900 (9th Cir. 1996) *cert. denied,* 117 S.Ct. 80, 136 L.Ed.2d 38 (1996); *Beno v. Shalala,* 30 F.3d 1057, 1073 (9th Cir. 1994). Thus, the scope under the arbitrary and capricious standard is narrow, and a court may not substitute its judgment for that of the agency. *Railway Labor Executives Assoc. v. Interstate*

Commerce Commission, 784 F.2d 959, 970 (9th Cir. 1986); *Dept. of Water and Power of the City of L.A. v. Bonneville Power Admin.,* 759 F.2d 684, 691 (9th Cir. 1985).

A hearing officer's factual findings are reviewed under the substantial evidence standard and reasonable factual inferences drawn by the officer are accepted. *Phelps Dodge Corp. v. OSHRC,* 725 F.2d 1237, 1239 (9th Cir. 1984). A fact finder's determinations are upheld "... if the record contains such relevant evidence as reasonable minds might accept as adequate to support a conclusion, even if it is possible to draw different conclusions from the evidence." *Loomis Cabinet Co.,* 20 F.3d at 941; *Landes Const. Co. v. Royal Bank of Canada,* 833 F.2d 1365, 1371 (9th Cir. 1987). The reviewing court will let the agency's decision stand if the evidence before the agency "provided a rational and ample basis for it." *Systech Environmental Corp. v. U.S. Environmental Protection Agency,* 55 F.3d 1466, 1469 (9th Cir. 1995) (quoting *Northwest Motorcycle Ass'n v. United States Dept. of Agriculture,* 18 F.3d 1468, 1471 (9th Cir. 1994).

Petitioners challenge the ALJ's Opinion on three grounds. First, they contend the ALJ applied the wrong standard of proof to the administrative review. (Doc. #13). Second, that he erred in finding Petitioners lacked proper authorization to use the LISTEN System to "practice" on patients for the FDA approved Biosource research study. (*Id.*). And finally, Petitioners contend that the ALJ erred in finding Petitioners were using the LISTEN System device for "diagnostic" purposes in order to induce follow-up tests and treatment. (*Id.*). The court will address these issues in turn.

B. *Burden of Proof: "Clear and Convincing" v. "Preponderance of Evidence"*

Petitioners initially argue that the ALJ applied the wrong burden of proof in affirming the alleged violations of the

Consent Decree. To wit, they claim that the ALJ erroneously characterized the proceeding as an administrative "assessment of damages" controversy requiring proof by a "preponderance of the evidence" as opposed to a civil contempt proceeding requiring proof of "clear and convincing evidence." (Doc. #13 at 26). While Petitioners are correct in their contention that civil contempt hearings generally require a showing of proof of a violation by "clear and convincing" evidence, they have misconstrued the intent and application of the standard by the ALJ.

1. ***Application of Standard***

The relevant standard of review is sometimes critical to the outcome of a case. *Payne v. Borg,* 982 F.2d 335, 338 (9th Cir. 1992)("The relevant standards of review are critical to the outcome of this case."), *cert denied,* 510 U.S. 843 (1993); *Walsh v. Centeio,* 692 F.2d 1239,1241 (9th Cir. 1982)("the outcome of the instant case turns on the standard of review"). Petitioners claim that this is true in this case. They contend the ALJ identified the applicable legal standard as a "preponderance of the evidence" or alternatively decided that the FDA's facts had to be "highly probable," and that he was wrong in both respects. (Doc. #13 at 21). Further, Petitioners maintain that had the "clear and convincing" standard of evidence been utilized they could never have been found in contempt.

While it is true the ALJ offered his opinion as to the nature of the hearing, he did so in a footnote, and nevertheless declined to determine which standard should govern the proceeding. The ALJ's Opinion states, "I do not need to reach the issue of which standard is applicable, giving that I find that FDA has proven its charges even under the judicial civil contempt standard of 'clear and convincing evidence.'" (Hearing Officer's Opinion, Adm. R. Vol. IX Ex. MM at 29).

In some cases, courts have elected not to decide which standard of review is applicable given that the outcome of the case would not change by applying a different standard of review. See, e.g., *In re Grand Jury Proceedings,* 87 F.3d 377, 380 (9th Cir. 1996); *Bicycle Trails Council v. Babbitt,* 82 F.3d 1445, 1456 n.6 (9th Cir. 1996); *United States v. Mendelsohn,* 896 F.2d 1183, 1185 n.1 (9th Cir. 1990). Moreover, the Supreme Court has suggested that it is "undesirable to make the law more complicated by proliferating review standards without good reason." *First Options of Chicago, Inc. v. Kaplan,* 514 U.S. 938, 115 S.Ct. 1920, 1926, 131 L.Ed.2d 985 (1995). In this case, the ALJ made the decision not to set a standard because it would not affect the outcome of the case. His opinion states, "[b]ased on the evidence, I find that the District has sustained its burden of establishing that Century Clinic violated the terms of the Consent Decree, whether the standard of proof is a preponderance of the evidence or clear and convincing evidence." (Hearing Officer's Opinion, Adm. R. Vol. IX Ex. MM at 29).

Notwithstanding his refusal to pinpoint a specific standard, the ALJ ultimately applies the higher burden of proof, that of clear and convincing evidence, in affirming the FDA's findings. The clear and convincing standard of proof requires evidence sufficient to reasonably satisfy the fact finder that it is highly probable the ultimate fact at issue happened. *See generally, Colorado v. New Mexico,* 467 U.S. 310, 315 (1984); *In re Dual-Deck Video Cassette Recorder Antitrust Litigation,* 10 F.3d 693 (9th Cir. 1993); *Vertex Distrib., Inc., v. Falcon Foam Plastics, Inc.,* 689 F.2d 885 (9th Cir. 1982). The ALJ found that Petitioners failed to comply with the specific terms of the Consent Decree. He found the terms of the Consent Decree were explicit and that Petitioners did not present *any* evidence, let alone substantial evidence, that would establish that they complied with the decree, nor any evidence that would

support that they took all "reasonable steps" to comply. (Hearing Officer's Opinion, Adm. R. Vol. IX at 29-30). In reviewing the entire administrative record and the ALJ's analysis, there is nothing to support the contention that the ALJ acted in an arbitrary or capricious manner by not specifying a standard of proof. To the contrary, there is sufficient evidence in the administrative record to provide a rational and ample basis for his decision not to do so.

2. *Deliberate Defiance and Willful Disobedience*

Petitioners support their position that the FDA could not find them in contempt by clear and convincing evidence by asserting that to prove non-compliance with or to find one in contempt of a consent decree, the violation must be made in "deliberate defiance and willful disobedience of the court." (Doc #13 at 27, citing *Falstaff Brewing Corp. v. Miller Brewing Co.*, 702 F.2d at 777-78, n.1). Petitioners would be right in this contention, if this were a criminal contempt hearing. "Wilfulness is an essential element of criminal contempt." *U.S. v. Armstrong,* 781 F.2d 700, 706 (9th Cir. 1986). However, this is not a criminal contempt hearing but rather one sounding in civil contempt. Wilfulness is *not* required for a finding of civil contempt, however, civil contempt may be based on wilful behavior. *U.S. v. Laurins,* 857 F.2d 529, 535 (9th Cir. 1988) *cert denied* 492 U.S. 906, 109 S.Ct. 3215, 106 L.Ed.2d 565 (1989)(Emphasis added). Petitioners contend that if they did stray at all from the provisions of the Consent Decree, the diversions were merely technical and were not intentional, wilful or deliberate. (Doc. #13 at 27-28). "An act does not cease to be a violation of law and of a decree merely because it may have been done innocently." *McComb v. Jacksonville Paper Co.*, 336 U.S. 187, 191, 69 S.Ct. 497, 499, 93 L.Ed. 599 (1949). Again, there is no scienter requirement for a finding of civil contempt. *Id.* Petitioners argument fails on this basis.

3. *Issues of Credibility*

Petitioners repeatedly emphasize that they have presented numerous witnesses who have testified under oath and have been subjected to cross-examination regarding the merits of this action, their professional ability, and the quality of their medical practice and patient record-keeping. (Doc. #13 at 17-19, 22, 41-42). According to Petitioners, they each complied fully with the terms of the Consent Decree and have always engaged in commendable services for those who desire and those who need homeopathic medical treatment. They have also presented numerous letters from satisfied patients in support of their medical competency. (Letters to Herb Ellingwood in Support of Century Clinic and Katrina Tang, Adm. R. Vol. VIII Ex. CC). In addition to promoting the reliability of their proffered evidence, Petitioners have attacked the credibility of respondent's case. Petitioners specifically challenge respondent's evidence as unverified, speculative, incomplete and unauthenticated. (Doc. #13 at 17-19, 22, 41-42). Petitioners argue the weight and credibility of their evidence alone is enough to override the FDA's burden of clear and convincing evidence. (*Id.*).

Questions of credibility and resolution of conflicts in testimony are addressed to the ALJ. *Russell v. Bowen,* 856 F.2d 81, 83 (9th Cir. 1988); *Sample v. Schweiker,* 694 F.2d 639, 642 (9th Cir. 1982). Decisions of ALJ's have not been reversed simply because the ALJ uniformly credited one parties witnesses in making his determinations of fact. *Jay Foods, Inc. v. NLRB,* 573 F.2d 438, 446, (7th Cir. 1978) *cert. denied* 439 U.S. 859 (1978). Great deference shall be given to credibility determinations made by the ALJ. *Sierra Club v. U.S. Nuclear Regulatory Com'n* 862 F.2d 222, 230 (9th Cir. 1988). "When substantial evidence supports ... a finding of fact and especially when the credibility of witnesses is involved, we [the court]

will not disturb that finding of review." *Dorris v. Director, OWCP,* 808 F.2d 1362, 1364 (9th Cir. 1987).

Although Petitioners disagree with any findings that may have been based upon unsworn FDA evidence, the agency is "... free in its exercise of expertise to give conflicting evidence whatever weight it deems appropriate in light of the accuracy and credibility of such evidence." *Babbitt,* 82 F.3d at 1463. As long as there is ample evidence supporting the agency determination, this court is not free to substitute its judgment for that of the agency. *Id.* The FDA has provided written summaries and transcripts of investigator Ritter's undercover investigation of Century Clinic in February 1994, as well as a memorandum of inspection conducted by five FDA employees on February 10-11, 1994. These documents form the basis for the finding of non-compliance. In addition, counsel for respondent participated in all depositions conducted by Petitioners, transcripts of which are included in the administrative review. In reviewing these depositions, the ALJ found that several of Century Clinic's witnesses provided conflicting versions of events, including how many times, by whom and for what purpose the LISTEN device was used. The ALJ further found that Century Clinic personnel occasionally altered their own statements, and some testimony, specifically that of Katrina Tang, was prompted or aided by attorney notes. The record reflects that when in possession of the notes, Dr. Tang testified from them verbatim. There is credible, accurate and substantial evidence throughout the administrative record, which includes submissions from both parties, on which the ALJ based his decision. Therefore, Petitioners argument that the ALJ's findings are unsupported by the evidence must fail. Under these facts, there is sufficient evidence to support the ALJ's conclusions. He sets forth specific facts, drawn from the record, in a detailed and comprehensive manner to support his decision throughout his opinion. He is entitled to weigh the

evidence and make his decisions accordingly. Here, he did so and his conclusions are supported by ample evidence in the record and are reasonable related to the agency action taken.

C. *"Practicing" with the Listen System Device*

Before turning to the merits of this issue, the court will address Petitioners argument that the ALJ failed to "give even lip service" to the FDA's applicable regulations before finding that "practice" was an unauthorized use of the LISTEN System under the Consent Decree. (Doc. #13 at 38). This contention is based upon the apparent ability of Biosource, as an authorized Sponsor, to be able to make changes and deviations from the Investigational Plan pursuant to 21 C.F.R. § 812.150(a)(4). In the proceedings before the ALJ, Petitioners failed to make this argument. Under the arbitrary and capricious standard, a reviewing court must consider only whether an agency's decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. *See Dioxin/Organochlorine Ctr. v. Clarke,* 57 F.3d 1517, 1521 (9th Cir. 1995). As such, if a party fails to raise an issue before the agency, that issue is waived, and, absent exceptional circumstances, that party is precluded from presenting it to a reviewing court. *Marathon Oil Co. v. U.S.,* 807 F.2d 759 (9th Cir. 1986), *cert. denied,* 480 U.S. 940, 107 S.Ct. 1593 (1987); *see also, Reid v. Engen,* 765 F.2d 1457, 1460 (9th Cir. 1985); *Bagues-Valles v. INS,* 779 F.2d 483, 484 (9th Cir. 1985). If an argument is not brought before the hearing officer, a reviewing court cannot determine the soundness of the judgment on that issue. This court will not address the merits of this challenge because Petitioners failed to raise this issue before the agency and further failed to note any exceptional circumstances that would warrant this court's review. As such, Petitioners have waived this argument.

Petitioners have raised several additional arguments to the "practice" claim that were reviewed by the ALJ. First,

Petitioners charge that the Biosource IDE protocol provided for and moreover required a training period which included practicing with the LISTEN System device on as many patients as possible. (Doc. #13 at 32-33). Further, Petitioners claim that during this training period they were not required to maintain records of the patients exposed to the device. (*Id.* at 34). Petitioners challenge the ALJ's finding that this practice was unauthorized. The ALJ found that even if the training period could be interpreted to include practice on human subjects, the device could still not be used, in any stage, without following IDE protocol and FDA regulations. (Hearing Officers Opinion, Adm. R. Vol. IX Ex. MM at 24). Further, the ALJ found that any permitted "practice" could only be to collect data for the diabetes study, not to test patients for various other diseases with the machine and the use of ampules. (*Id.*).

The court cannot find that the ALJ's finding that Petitioners' use of the LISTEN System device for practice was an unauthorized use was arbitrary or capricious. Rather, the finding was eminently reasonable. Petitioners repeatedly place blame on Biosource, the diabetes metillus study Sponsor, for their actions. However, Biosource did not voluntarily entered into a court approved consent decree, and is not bound by its terms. Petitioners did and are. As the ALJ notes, relying solely on the Sponsor is not a justifiable excuse for straying from the provisions of the decree. Petitioners admit they didn't contact the FDA directly regarding the diabetes study protocol or Biosource IDE. (Deposition of Herbert Ellingwood, Esq., Adm. R. Vol. II at 114). In addition, Dr. Tang admits that during the practice period she did not follow the Biosource IDE. (Deposition of Katrina Tang, M.D., H.M.D., Adm. R. Vol. I at 150-151). Further, Willis Clark, IRB monitor for the Biosource training program failed to inform the FDA that patients were being used for practice on the device, and does not recall any correspondence regarding practicing on patients. (Deposition of Willis Clark, Adm. R. Vol. V at 89-90). Contrary to

Petitioners assertions, the record provides sufficient evidence to support the ALJ's determination that Petitioners did not take "all reasonable steps within [their] power to insure compliance," with the Consent Decree. (Hearing Officer's Opinion, Adm. R. Vol. IX at 27).

The ALJ also considered Dr. Tang's use of ampules of homeopathic solutions, during "practice" on patients. He found, and there is no dispute, that these ampules had nothing to do with the diabetes study, but rather could balance energy readings dealing with other diseases including, but not limited to, Parvo, Hepatitis and Epstein Barr syndrome. Again, petitioners defend the use of the ampules by stating that they were instructed to use them at the Level I training by Biosource. (*Id.* at 36). However, Dr. Tang admitted that she learned to use the ampules by watching several other doctors, prior to the Biosource study, and could not remember such instruction being given at the Level I training. (Deposition of Katrina Tang, Adm. R. Vol. I Ex. A, at 252-254). Collectively, the ALJ determined that this evidence was sufficient to prove petitioners violated the Consent Decree. He found that the Clinic's "practice" including use of plates and ampules was not described in the investigational plan, and as such Sponsor approval was not enough and FDA approval, which was never sought, was necessary. The ALJ's determinations with respect to the issue of "practice" are grounded on reasonable inferences drawn from the facts. He did not act arbitrarily in affirming the FDA's notice of violations in this respect.

D. *Use of the LISTEN SYSTEM Device for Diagnostic Purposes*

Petitioners contend that the LISTEN System device was never used for diagnostic purposes, and further that it cannot be used for such purposes as it is not a diagnostic machine, rather an indicator, much like a thermometer. (Doc. #13 at 42). Petitioners attack the credibility of the FDA's evidence on this

issue and maintain that any patient diagnosis occurred prior to his or her exposure to the LISTEN System device. (*Id.* at 44). Contrary to petitioners' position, the ALJ found that the evidence conclusively established, "... the clinic used the LISTEN System for the purpose of determining whether it appeared that patients had serious diseases and conditions, which findings the patients were told would need to be verified by (expensive) tests." (Hearing Officer's Opinion, Adm. R. Vol. IX Ex. MM at 13).

The facts suggest that there is conflicting evidence as to when and how the LISTEN device was used by Century Clinic. Most of the conflicts occur within petitioners' evidence. As noted before, six different employees were interviewed by FDA investigators prior to finding any violations of the Consent Decree. These six employees each told different stories relating to the frequency and purpose of the use of the machine. In addition, it is undisputed that after examining Investigator Ritter, Dr. Tang recommended expensive follow up tests for a variety of health problems. A number of these tests corresponded with abnormalities discovered by the LISTEN System device while screening Investigator Ritter. For instance, Dr. Tang recommended Investigator Ritter undergo a blood test to detect aluminum in her system. Dr. Tang's discovery of any presence of aluminum in Ms. Ritter's system occurred during the screening process on the LISTEN System device. It is clear that the recommendation for a blood test for aluminum, as well as all other tests, was made subsequent to that procedure. Petitioners argue that Dr. Tang did not offer any diagnosis regarding the imbalanced conductance readings suggesting exposure to copper and aluminum. However, Dr. Tang did recommend a follow-up test involving the same. It was not unreasonable for the ALJ to infer from these facts that the tests were prompted by "indications" from the LISTEN System device. It is much more unlikely that Dr. Tang would recommend the aluminum test prior to some indication of the

presence of the metal. The ALJ also noted that Dr. Tang stated that, "the LISTEN System device could be used to detect infections, inflammations and cancer." (Hearing Officer's Opinion, Adm. R. Vol. IX at 14-15). In fact, after the device would "indicate" a certain disease may exist, such as hepatitis, Dr. Tang would place ampules on a metal plate on the device to see whether the correlating solutions would normalize the readings. Here again, it is reasonable to infer that if the device can detect various diseases, and the solutions in the ampules can normalize the readings, the device can be used in part to formulate a diagnosis or at least to prompt the recommendation of follow-up exams. In fact, Willis Clark, IRB Monitor for the Biosource admitted that a person may find LISTEN information helpful in making a total diagnosis. (Deposition of Willis Clark, Adm. R. Vol. V at 109). There is ample evidence in the record to suggest Dr. Katrina Tang used the LISTEN System device in part to articulate her final diagnosis of a patients condition or at least to confirm prior diagnosis or suggest follow-up testing. The ALJ did not act in an arbitrary or capricious manner in affirming this finding.

III. *CONCLUSION*

There was substantial evidence before the ALJ to determine that the FDA had sufficient factual support for its determination that Petitioners had violated the March 23, 1993, Consent Decree. The evidence in the administrative record established that as a result of Complaints filed by the FDA, Petitioners entered into a consent decree resulting in an agreement to refrain from using various medical devices, specifically here the LISTEN System device, unless an approved application for pre-market approval ("PMA"), pursuant to 21 U.S.C. § 360(e), or an approved application for an investigational device exemption, pursuant to 21 U.S.C. § 360j(g), authorized their use of such devices. The evidence further established that Petitioners engaged in such prohibited

activity after entering into the Consent Decree. There is no dispute that a PMA for the LISTEN System device was never filed and there is ample evidence in the administrative record to show unauthorized use of the device, under the Biosource IDE and FDA regulations. Such facts constitute substantial evidence of Petitioners violations of the decree. Viewing the Consent Decree in its entirety, together with the complete administrative record, the ALJ concluded that Petitioners violated both the letter and the spirit of the Consent Decree. In affirming the violations and imposition of penalties, the ALJ did not act in an arbitrary or capricious manner.

IV. *RECOMMENDATION*

IT IS THEREFORE RECOMMENDED that the District Court enter its Order ***AFFIRMING*** the ALJ'S decision finding non-compliance with the Consent Decree and assessment of monetary penalties in the amount of four hundred thousand dollars ($400,000.00).

DATED: February 3, 1998.

/s/ Robert A. McQuaid, Jr.

UNITED STATES MAGISTRATE JUDGE

APPENDIX D

PRESIDING OFFICER OPINION IN UNITED STATES v. CENTURY CLINIC, INC., ET AL.

I. *BACKGROUND*

On March 24, 1993, a Consent Decree of Permanent Injunction ("Consent Decree") was entered in the United States District Court for the District of Nevada permanently enjoining Century Clinic, Katrina Tang, H.M.D., Yiwen Tang, M.D., their officers, agents, servants, employees, and attorneys, from, among other things, using the LISTEN System device (among other devices) unless either an approved application for a premarket approval (PMA), pursuant to 21 U.S.C. § 360(e), or an approved application for an investigational device exemption (IDE), pursuant to 21 U.S.C. § 360j(g), authorized the defendants' use of the device. *See* Consent Decree at ¶¶3(A). Under the Decree, if the United States Food and Drug Administration ("FDA") finds that the defendants have violated its terms, defendants are required to forfeit $200,000.00 per violation, after written notice of such violations and an opportunity by defendants to challenge that determination. *Id.* ¶¶10.

This current action involves defendants' alleged use of two LISTEN System devices in violation of the Federal Food, Drug, and Cosmetic Act ("Act") and the Consent Decree. The LISTEN System device (Life Information System TEN) is the subject of a conditional investigational device exemption ("IDE"),[1] held by Biosource Inc. (Biosource), of Orem,

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[1] As this opinion will describe in more detail, all devices initially marketed after May 28, 1976, must be subject to FDA premarket approval ("PMA"), a "510(k)" order finding substantial equivalence to a pre-76 device, or an investigational device exemption ("IDE"). An "IDE" permits the unapproved device to be used only for the investigational use(s)

Utah.[2] Biosource submitted an application for an IDE for the LISTEN System device on August 6, 1993,[3] and the Center for Devices and Radiological Health ("CDRH"), FDA, conditionally approved the IDE on September 10, 1993. *See* Defendants Exhibit ("Def. Exh.") N.[4] Century Clinic is a study site for the clinical investigation of the LISTEN System device under the Biosource conditionally approved IDE.

The Biosource IDE permits the LISTEN System device to be used, pursuant to the approved study protocol and FDA regulations, in a study for the collection of electrical conductance data for comparison to blood glucose levels for

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described in the FDA approved application, or pursuant to Institutional Review Board ("IRB") approval where applicable, following the IDE regulations. Use of an unapproved device outside of these channels is strictly prohibited.

[2] James Clark, of Biosource, is the developer of the LISTEN System. Willis Clark, also of Biosource, is the study monitor for the Biosource conditionally approved IDE.

[3] Biosource initially sponsored studies with the LISTEN System device under FDA's abbreviated requirements in 21 C.F.R. § 812.2(b), which permit the use of a "non-significant risk" device pursuant to IRB approval without formal submission of an IDE to FDA, unless FDA notifies the sponsor that FDA approval of an application is required. FDA required Biosource to submit a full IDE by letter on June 28, 1993, however. Once FDA requires that an IDE application be submitted to the agency, the *only* permitted use of the device is the use approved by FDA in the IDE. *See* 21 C.F.R. § 812.2(b) (the abbreviated requirements apply *unless* FDA notifies a sponsor that approval under § 812.20(a) is required); 21 C.F.R. § 812.20(a) (a sponsor is required to submit an IDE whenever FDA notifies the sponsor that it is required).

[4] Since conditionally approving the IDE, CDRH has cited a number of serious deficiencies in the IDE, has requested further clarifications on the material submitted in the IDE, and has proposed to withdraw the IDE because it believes that the diabetes investigation is fundamentally and scientifically unsound. *See* Def. Exh. O.

patients with and without diabetes mellitus. The purpose of the IDE study "is to determine if the BEM [bioelectromagnetic] screening data can differentiate subjects that have insulin dependent diabetes from subjects that have normal glucose levels without insulin." *See* IDE Application, Def. Exh. M at Investigational Plan, 1.

II. *THE CURRENT CHARGES*

By letter dated February 25, 1994, to William F. McCormick, President, Century Clinic, the FDA San Francisco District Office ("District") notified Century Clinic, Inc., Katrina Tang, M.D., H.D.M.,[5] and employees of the Clinic, Rosario Quintana and Herbert Ellingwood, Esq., that they had violated the Consent Decree by using the LISTEN System devices outside of the study permitted under the Biosource IDE[6] and were required to forfeit $400,000.00.[7]

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[5] All references to "Dr. Tang" in this opinion are to Dr. Katrina Tang, M.D., H.M.D. Dr. Katrina Tang's husband, Dr. Yiwen Tang, is alleged to be no longer practicing medicine or connected with the operations of Century Clinic. *See* Consent Decree at ¶ 13.

[6] There is no dispute that Century Clinic does not hold a PMA for the devices.

[7] The February 25, 1994, Letter; April 5, 1994, Memorandum from Beverly Ritter, FDA Investigator regarding Conversations recorded at Century Clinic, February 9, 1994 (hereinafter "Transcript of Undercover Investigation"); April 5, 1994, Memorandum from Beverly Ritter regarding a chronology of Century Clinic undercover work 1/24/94-2/23/94 (hereinafter "Chronology Memorandum"); April 8, 1994, Memorandum from Compliance Branch, FDA San Francisco District Office regarding the 2/10-11/94 inspection, entitled "Summary of Findings" (hereinafter "Inspection Memorandum"), and an April 11, 1994, Memorandum from the Director, Compliance Branch, FDA San Francisco District Office, entitled "Contempt of Injunction," set forth the facts presented by the District.

The District alleges that Century Clinic used Biosource's IDE as a facade to continue the illegal practices that gave rise to the entry of the Consent Decree, namely, using an acupuncture type device to "diagnose" various serious illnesses and conditions and induce patients to obtain expensive follow-up tests. The District asserts that Century Clinic did not gather either the conductance screening data called for by the IDE or the blood glucose levels for comparison to the screening data, which was supposed to be compared to determine whether the devices could indicate whether a subject had diabetes mellitus, the only permitted purpose of the study. Instead, the District claims that Century Clinic used the devices (with attachments of ampules of medicines not covered by the IDE) to diagnose whether patients had various diseases, for example, cancer, HIV, Hepatitis, and Epstein Barr, among others. *See, e.g.*, Transcript of Undercover Investigation; February 25, 1994, Letter at 3; *see* April 11, 1994, Memorandum, at 4-7; *see also* April 8, 1994, Inspection Memorandum at 3, 5-12; April 5, 1994, Chronology Memorandum at 2-6. The District also states that Century Clinic used the devices in this manner without following the IDE regulations and keeping the records required of a clinical investigator under those regulations. *See* February 25, 1994, Letter at 2-3; April 11, 1994, Memorandum at 5.

Century Clinic responds that it was using the LISTEN System devices under Biosource's IDE correctly, and that it did not need to follow the IDE protocol or keep records required by the IDE regulations because it was just practicing with the devices on patients prior to the start of the research. In addition, Century Clinic argues that the District did not provide Century Clinic with proper notice of the alleged violations of the

Consent Decree,[8] illegally conducted an undercover investigation of the Clinic, and failed to meet its burden of proof in establishing violations of the Consent Decree.[9]

III. *STATUTORY AND REGULATORY SCHEME*

Under the Act, a device introduced into commerce after the date of the enactment of the Medical Device Amendments of 1976 (May 28, 1976) must be approved by FDA in the form of an approved application for premarket approval ("PMA") pursuant to 21 U.S.C. § 360(e), found substantially equivalent to a device on the market prior to the date of the enactment of the Amendments or to a post-amendment Class I or II device (a

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[8] Century Clinic asserts that the District has only alleged and provided notice that they violated the Consent Decree by using the devices for "diagnostic" purposes. The Clinic believes that if they rebut that claim, they have proven that they have not violated the Consent Decree. I find, however, that the District provided proper notice to the Clinic, Dr. Tang, and employees that they violated the Consent Degree by using the devices outside of an approved IDE or PMA. In fact, the February 25, 1994, Letter to Century Clinic, which was only one document among several provided to Century Clinic to explain the violations, explicitly states that defendants are found to be in violation of the Decree "by using the LISTEN System outside of the approved IDE." *Id.* at 3. The reasons presented by the District to Century Clinic for this finding were that the device was not used to collect information related to differentiating insulin dependent diabetics from "normal" patients in accordance with the IDE and following the IDE regulations, but to determine whether it appeared that patients had serious diseases and conditions (after which expensive tests would be recommended to validate those impressions). *See, e.g.*, February 25, 1994, Letter at 2-3; April 8, 1994, Inspection Memorandum; and April 11, 1994, Memorandum. Century Clinic was clearly on notice that the District was alleging that it had used the devices outside of the scope of the conditionally approved IDE and this opinion proceeds accordingly.

[9] *See, generally,* Century Clinic's Memorandum in Opposition to FDA Notice of Non-Compliance; Century Clinic's Memorandum of Law; Transcript of oral presentation dated June 29, 1994; and Century Clinic's Reply Memorandum in Opposition to FDA's Notice of Non-Compliance.

"510(k) order"), or exempted from such approval requirements by an approved application for an investigational device exemption ("IDE"), pursuant to 21 U.S.C. § 360j(g).

The purpose of the IDE provision in the Act is to permit unapproved devices to be used in investigational studies on human subjects, in a safe and carefully controlled manner, to determine their safety and efficacy for a particular use. FDA promulgated regulations, set forth in 21 C.F.R. Part 812, that establish the strict conditions under which such investigational studies may be conducted with unapproved devices. The main objectives of the IDE regulations are to protect the health and preserve the rights of persons that will be subjected to the investigational devices and to ensure that data collected from the use of the devices will be reliable, while encouraging the discovery and development of useful medical devices. *See* 41 Fed. Reg. 35,282 (Aug. 20, 1976).

Accordingly, the regulations, among other things, permit the unapproved devices to be used only in accordance with the approved IDE and the IDE regulations. The IDE application the sponsor submits to FDA must explicitly detail the intended use of the device, the objectives of the study, and the protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound in the Investigational Plan. *See* 21 C.F.R. § 812.25. The IDE must also include a description and analysis of all increased risks to which subjects will be exposed and a description of each important component, property, and principle of the device. *Id.* In addition, the regulations require the use of a device under the IDE to be carefully monitored, 21 C.F.R. § 812.46, investigators and monitors to be qualified, 21 C.F.R. § 812.43, and the specific responsibilities of investigators to be defined by both a signed agreement between the investigators and the sponsor and the Investigational Plan, 21 C.F.R. § 812.110. Investigators using the devices are

required to conduct the investigation according to the signed agreement, investigational plan, the applicable FDA regulations. 21 C.F.R. § 812.100. Investigators also must keep records on each use of the device on a patient, 21 C.F.R. § 812.140, and obtain Informed Consent from each patient on whom the device will be used, 21 C.F.R. § 812.100 and Part 50. The regulations also explicitly state that before obtaining FDA, or IRB approval (where applicable), to begin a study, an investigator shall not obtain written informed consent from a subject or begin the study. 21 C.F.R. § 812.110.

Thus, an unapproved device may only be used subject to an approved IDE, following the protocol for which the IDE has been approved, and following the requirements in the IDE regulations. The existence of an IDE for a particular use for a device does not provide a legal avenue for using the device for all (or any) other purposes. If a device is used in a manner not permitted in the IDE, without following the IDE regulations, the device is not used subject to an approved IDE. Such a device would be adulterated under 21 U.S.C. § 351(f)(1), among other things, for lack of FDA approval.[10] *See, e.g.*, 45 Fed. Reg. 3,732 (Jan. 18, 1980).

IV. *FINDINGS*

I find that Century Clinic's use of the LISTEN System devices bore no resemblance to the use permitted by the Biosource conditionally approved IDE and the IDE regulations. Century Clinic did not apply for and receive premarket approval for its use of the LISTEN System device. Therefore, after a careful consideration of the applicable law, regulations, and administrative record in this matter, as discussed below, I

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[10] Century Clinic's statements to the contrary, *see* Century Clinic's Memorandum in Opposition to FDA Notice of Non-Compliance n. 52, at 19 and 17-18, are incorrect.

affirm the San Francisco FDA District Office's finding that Century Clinic violated the terms of the Consent Decree by using the LISTEN System device without an IDE or PMA authorizing such use.

A. *The Biosource IDE*

Whether Century Clinic violated the Consent Decree turns on how the Clinic used the devices. If Century Clinic used the devices as permitted by the conditionally approved IDE and IDE regulations, it has complied with the Decree. If the Clinic used the LISTEN System devices for a purpose other than that permitted by the IDE, or without complying with the IDE regulations, it used the devices without the required FDA approval and violated the Consent Decree. *See supra,* at 6-7.

Under the IDE, the LISTEN System device is described as a "computerized data acquisition device for measuring conductance with a library base of electromagnetic fields. The components of the LISTEN System are a computer, Input/Output Interface Card, conductance electrode set, and software." Def. Exh. M, Investigational Plan at 41; *see also* Gov. Exh. 3 (IDE Supplement) at 1, 11-13. Briefly, the device is a computer with attached brass electrodes that are used to measure the electrical resistance at different places (conductance points) on the body. *See* Investigational Plan at 33, 44-46. The computer displays diagrams of parts of the body to illustrate the locations on the body that are listed in the software. *Id.* at 46.

The Investigational Plan conditionally approved by FDA states explicitly that the study "uses the LISTEN System from Biosource to collect data." *Id.* at 33. The purpose of the use of the device under the study is to see whether the conductance data collected with the device can be used to determine whether a patient has insulin dependent diabetes. *Id.* at 1. The IDE states that the data to be collected under the study are the conductance

data, the blood glucose levels, and whether the patient is insulin dependent or normal. *Id.* at 2. The analysis was to compare "the conductance data using the screening protocol to the blood glucose levels of a test group and a control group." *Id.* The IDE states that "[t]he hypothesis of this study is that [the device] can be used to screen carbohydrate metabolism imbalance in insulin dependent and healthy subjects." *Id.* at 32. The IDE further states that the device is *not* intended to be a diagnostic tool. *See, e.g., id.* at 4.

The IDE discusses training investigators to use the device under the "Monitoring Procedure" section. The IDE provides for two training classes, Level I and Level II. The IDE provides that the Level I class will include instruction on FDA IDE regulations, the research protocol, computer literacy, and the operation of the LISTEN System. It states that Level I Certification may be obtained by establishing satisfactory skill at taking conductance measurements. It further states that after Level I Training, each clinical investigator must send in 25 cases studies, which will be reviewed for data collected, overall consistency, and "number of high or low data." *Id.* at 54. The IDE states that the Level II Seminar will include lectures by various professionals, among other things. Level II Certification would cover all that was presented in both Level I and II classes. The IDE states that both Certifications are required of research participants. *Id.* at 55.

The Research Participant agreement, submitted with the IDE, provides that an investigator under the IDE is required to 1) become a site for the LISTEN System (which meant paying Biosource $15,500.00 for each device), 2) attend the Basic Training Course, 3) submit 25 case studies following the research protocol within the first 90 days after taking the class, 4) become certified, and 5) submit 10 test subjects and 10 controls during one year, with data being submitted about once a month.

B. *Century Clinic's Use of the LISTEN System Device*

Thus, the conditionally approved Biosource IDE permitted use of the LISTEN System solely for collecting data from the 70 conductance points on the body (*see* Def. Exh. M., Append. B), which data was to be compared with the fasting blood glucose level of the tested patient. Use of the device for any other purpose, or in any way not in accordance with the provisions of the IDE, would be use without required FDA approval.

It is now undisputed that Century Clinic used the two LISTEN System devices located at the Clinic[11] on many patients (at least half of all new patients and on repeat patients who "requested" its use, Tang Dep., at 99-100)[12] without collecting *any* conductance data and or blood glucose levels for *any* patients for approximately nine months. The Clinic has

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[11] *See* discussion, *infra* at 29-30, regarding the number of devices in use at the Clinic.

[12] When FDA investigators first questioned Century Clinic employees regarding their use of the LISTEN System devices, many conflicting responses were provided. Dr. Tang first informed FDA investigators that she did not really use it, stating "most of the time, I don't use it on new patients anymore - too clumsy." April 8, 1994, Inspection Memorandum, at 5. She later told investigators that she never used the LISTEN System. *Id.* The Clinic's in-house attorney, Mr. Ellingwood, stated that the Clinic used the device on every, or nearly every, patient. *Id.* The nurse, Ms. Quintana, told investigators that Dr. Tang used the device on patients who were curious about it, and only one or two new patients within the last three months. *Id.* at 7. She also told investigators that the last time she had seen Dr. Tang test a patient with the device was two weeks before the inspection, *id.*, even though she had assisted Dr. Tang in Investigator Ritter's examination two days earlier. *Id.* at 7. Ms. O'Gorman told FDA investigators that ten to twenty patients out of 100 are tested with the device. *Id.* at 10.

admitted this.[13] Instead, as the District's undercover investigation, subsequent investigation conducted on February 10-11, 1994, and testimony by Century Clinic conclusively establish, the Clinic used the LISTEN System for the purpose of determining whether it appeared that patients had serious diseases and conditions, which findings the patients were told would need to be verified by (expensive) tests.

For example, the following discourse occurred during Dr. Tang's examination of Investigator Ritter, which was taped by Investigator Ritter[14] during her undercover investigation at the Clinic.[15] First, Dr. Tang informed Investigator Ritter that the

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[13] *See, e.g.,* Tang Dep. at 56-57, 141-142, 238. Under direct examination, Dr. Tang had originally testified that Century Clinic had two LISTEN System devices and that both were used to *"gather information."* Tang Dep., at 44-46. It was disclosed during cross-examination that her earlier testimony was given with the assistance of notes written by her attorney. *Id.* at 105-108. Dr. Tang also admitted that no record is made of the date and time of exposure of the patient to the device, as required by the IDE regulations, 21 C.F.R. § 812.140(a)(3). *Id.,* at 134-140; 238. Other members of the Clinic and Biosource confirmed that records required to be kept pursuant to 21 C.F.R. § 812.140 were not kept. *See* Def. Exh. P., Carlson Dep. at 78-79; Ellingwood Dep. at 27, 35-36, 89-93; James Clark Dep. at 110; Willis Clark Dep. at 52-53.

[14] Investigator Ritter was unable to record the consultative portion of her visit to Century Clinic. However, she began recording before the physical exam and recorded Dr. Tang's use of the LISTEN System device on her and the subsequent discussion with the nurse, Ms. Quintana. *See* April 15, 1994, Chronology Memorandum, at 2-4.

[15] Century Clinic challenges Investigator Ritter's undercover investigation as a violation of the terms of the Consent Decree, which they claim authorizes FDA to enter and inspect the Clinic for purposes of monitoring compliance *"only* 'upon presentation of a copy of this Decree and appropriate credentials.'" *See* Century Clinic's Memorandum in Opposition, at 23 (emphasis in original). I find this assertion wholly without merit. (cont'd)

device was not "a diagnostic machine" but "an indicator, like a compass," (*see* Def. Exh. DD, Undercover Investigation Transcript, at 7). She then proceeded to state that the LISTEN System device could detect infections, inflammations, and cancer:

> KT: '....OK when-when the graph comes down when I check you, if in the green zone, that means you're normal and if any infections any irritation or inflammation, they go high. But-but degeneration or cancer they go low, I check you ####'[16]

Contrary to Century Clinic's assertion in its Memorandum in Opposition, the word "only" does not appear in the Consent Decree. The Decree in no way limits FDA's right to conduct *any* type of investigation or inspection permitted by law. In fact, the Consent Decree specifically states: "Such inspection and patient record access authority granted by this Decree is apart from, *and in addition to,* the authority to make inspections under the Act, *e.g.,* 21 U.S.C. § 374, or the regulations, *e.g.,* 21 C.F.R. § 812.145, or any other applicable provision of law granting such authority." Consent Decree, ¶¶7 (emphasis added). It is clear that FDA attempted to ensure by the Decree that its inspectors would be not be denied access to the clinic, not to limit its own authority.

[16] The designation "####" means that portion of the tape recording is inaudible. The "Beep" designation refers to a beep sound that the LISTEN System device makes as Dr. Tang touches Investigator Ritter with the probe on her fingers and toes. At some places in the transcript, the #### mark is struck and words are added in parenthesis to the transcript based on what it is believed was said. FDA attempted to enhance the tape recording by sending it to a Federal Bureau of Investigation (FBI) lab for digital enhancement. *See* Def. Exh. DD, Undercover Investigation Transcript, at 1, 7; *see also* April 11, 1994, Memorandum, at 6.

The designation KT refers to Katrina Tang; BR refers to Beverly Ritter; and N refers to Rosario Quintana (nurse). *See* Def. Exh. DD, Undercover Investigation Transcript, at 1; *see also* April 8, 1994, Inspection Memorandum, at 7.

KT: 'But in this country it's not legal to use unless you using #### for research. That's why you signed that form for me to touch you. These points like this black mark - OK. Each point is connected to one other internal system inside you there. Because you know our body cells #### cancer'

Id. at 7.

At her pancreas, Dr. Tang states:

KT: 'And at this point its hypoglycemia. Hypoglycemia is low sugar, opposite of diabetes, ...'

Id. at 9-10.

And then:

KT: 'Everything else is normal except your lymphatic system, circulatory (system), and you're nervous system. Circulation, allergies, liver, spleen, and pancreas. #### now we have to find out why it is OK because your symptoms mostly is nerves ....'

Id. at 13-14.

KT: 'From your symptoms based on my experience is uh ever since nineteen eighty - nineteen eighty-six the Epstein Barr virus (we have seen a lot of patient with it.) Lets try and check Epstein Barr virus. That how you check it for Epstein Barr virus. That is the medicine for Epstein Barr Virus. ####'.

Beep

KT: 'Then I put it on'[17]

Beep

KT: '-your nerves really clam down.'

KT: 'Then I take off'

Beep

Beep

KT: '-that means your body must carry the same thing because identical energy pattern for each one you must have the same #### same pattern as Epstein barr virus or you can say if we use this medicine on the plate it seems to calm your nerves.'

Id. at 14-15.

KT: 'Check Hepatitis'

Beep

Beep

KT: 'Oh hepatitis.'

Beep

Beep

BR: 'Which Kind'

KT: 'A - now we check B'

Beep

Beep

KT: '(Oh!)'

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[17] At this point, Dr. Tang placed vials (ampules) of medicine or solutions on a metal plate on the Listen System device.

KT: 'Hepatitis. When you were young just A and B now ABCDE C normally young generation has. ####' '(Now test C)'

Beep

KT: '(You don't match.)'

Id. at 16-17.

KT: 'This I already found it on your tongue - yeast infection.'

Beep

KT: 'Chlamydia 1.'

Beep

KT: 'Chlamydia 2.'

Id. at 17.

KT: 'We're checking HIV now. AIDS - it's four categories. The first two are pre-AIDS - HIV - 1 and 2. Sometimes it's like six, seven, or thirteen years #### of course these airborne. And HIV-3 is the real gay AIDS. And there's another tribe, SV 4 is supposed to be carried by blood transfusion. We're checking HIV ####.'

Beep

KT: 'HIV ####"

Id. at 18.

KT: 'Somehow, you have to tell it. Your immune system is confused by it - overdose vaccination. I can still find it. So you have tendency to be hypoglycemic, they lower the adrenal system. Adrenal is the one control the immune cells the

one who produce your insulin. You're producing too much insulin and - and then you have a tendency craving starch or sugar.'

Id. at 23.

KT: 'And because this indicator even told me you been exposed to a little copper and aluminum.'

Id. at 24.

BR: 'Now what?'

KT: 'Now we have to treat the viruses and all your infections and desensitize all the chemicals, heavy metals and the overdose vaccination.'

Id. at 25.

After Dr. Tang concluded testing Investigator Ritter with the Listen System device, a nurse, Ms. Quintana ("Ging-Ging"), re-entered the examination room to speak to Investigator Ritter about further testing. The following discussion was recorded:

N: '....I'll talk to you about further testing the doctor needs you to go through. Now let me tell you what these tests are and then I will let you decide if you want to go. First of all the doctor wants you to have a circulation test, OK, when she checked you here it showed that you have a problem with your ####. Now the circulation test will tell us if you do have a blockage and which part of your body. Now these would include your heart and your lungs. And that would be $535. Then she is also suggesting allergy tests. You know you have allergies. Now she needs you to have allergy tests, food and inhalant allergy test. Now these are done by a blood test and a skin test. The blood test part would show how much

allergies you have. The skin test part would tell us how strong the medication will be. Now food allergy test is $300. Inhalant allergy, they are allergies to things in air like house dust, spore, molds, grasses. And for people living in California that's $496, and this is just the price of testing. This does not include any treatments or medication at all.'

BR: 'Um huh, OK.'

N: 'And then we need you to have a regular blood test done on your cholesterol triglycerides, your liver function, kidney function. Which is $50. *But as the doctor told you this is just her indicator. Now we are required to confirm by blood test all the herpes part which she found including the hepatitis part.* Later on, I'll give you a paper that tells you how much each of these blood testings will cost. And then she wants you to have chemical sensitivity testing that's a blood test which show the degree of exposure you have - to, formaldehyde, latex, all the chemicals. And it's $150. And she wants to have a blood test for the aluminum. This would tell us the degree of aluminum in your system, and that's $120.'

See Def. Exh. DD, Undercover Investigation Transcript, at 27-28 (emphasis added).

The transcript makes clear that Dr. Tang used the device to determine whether Investigator Ritter had various conditions and diseases. For example, Dr. Tang told her patient that if she had cancer, the readings on the machine would "go low." *Id.* at 7. She also told Investigator Ritter that the device would check her for Epstein Barr virus, *id.* at 14-15, hepatitis, *id.* at 16-17, and HIV, *id.* at 18. In addition, Dr. Tang informed her patient

that the device told her that she had been exposed to copper and aluminum. *Id.* at 23. After the testing, Dr. Tang informed Investigator Ritter that she would have to treat the viruses and infections, and "desensitize" the chemicals and heavy metals. *Id.* at 25. The nurse told Investigator Ritter, among other things, that because the device was just Dr. Tang's "indicator," they were required to confirm by blood test many of the findings, including the herpes, hepatitis, and aluminum. *Id.* at 27-28.

During her deposition, Dr. Tang testified that the device has an established "normal" zone. *See* Tang Dep. at 246. She stated that she uses the ampules with the medicine and solutions when testing patients with the LISTEN System device to determine whether the reading will normalize with the ampules. *See, e.g.,* Tang. Dep., at 246-249; 261-63 (Dr. Tang testified that she places vials for Hepatitis A & B, Epstein Barr virus, HIV 1 & 2, and other conditions such as Russian pleuritis, on the device).[18] Not only does this use to which Dr.

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[18] When questioned regarding how she learned to use the ampules, which are nowhere described as part of the IDE study, Dr. Tang testified that she could not recall whether Biosource had trained her to use the ampules of medicines, and that she had learned by "watching other doctors." *Id.* at 250-252. Witnesses for Dr. Tang and the Clinic testified, after Dr. Tang, that the use of the ampules was intended and permitted by the IDE (although not mentioned in the protocol), and that Biosource *had* instructed Dr. Tang to use the ampules, facts of which Dr. Tang had no recollection.

Regarding her faulty memory, Dr. Tang testified that she had suffered a heart attack that affected her short and long-term memory. *Id.* at 109-113. Thus, she testified that she could not remember testifying earlier the same day regarding the Consent Decree, *id.* at 109, although she claimed to have full recollection of the events that occurred on the day she examined Investigator Ritter, challenging particular statements in the transcript and recounting that she had already "diagnosed" Ms. Ritter's conditions before using the LISTEN System device on her. *See, e.g., id.* at 115-133; *see also* Ellingwood Dep., at 44-45 (also alleging that parts of the transcript of the examination of Investigator Ritter are incorrect, even though he has "never been in the room when a patient is questioned or treated.").

Tang put the LISTEN System have no relevance to the diabetes IDE Investigational Plan, but a fasting blood glucose level was never obtained on Investigator Ritter. And, as noted earlier, no conductance data was collected for any comparison to the blood glucose test, had it been obtained. *See, supra,* at 12-13. Further, use of the devices in the manner employed on Investigator Ritter was not an isolated incident. The Clinic testified that it had been using the devices in this manner, employing use of the ampules, without collecting conductance data or blood glucose levels, i.e., without following the Investigational Plan, for approximately nine months. *See, e.g.,* Tang Dep., at 46-48; Ellingwood Dep., at 149-150; *see also* n. 13 at 12-13.[19]

C. *Century Clinic's Defense*

Century Clinic defends its use of the LISTEN System devices in the manner described above by claiming that the IDE permitted the testing they performed, with the use of the solutions containing viruses and chemicals. They also assert that they were not required to follow the approved protocol (collecting the conductance data and the blood glucose levels), or the IDE regulations, because they were just "practicing" with the devices prior to beginning research. Century Clinic also asserts that because Biosource allegedly told them that this use of the devices was permitted, even if it was not, they cannot be held liable.

1. *Testing for various diseases*

Century Clinic could not identify where the IDE states that the devices could be used, with the attachments of ampules of solutions, to check patients for various diseases. *See, e.g.,* Ellingwood Dep., at 80 ("There's nothing in this document

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[19] In addition to 21 C.F.R. § 812.140 (a) (3), the Clinic also failed to follow section 812.100, which requires that clinical investigators follow the Investigational Plan and IDE regulations.

[IDE] that I know of."). They argue, however, that FDA has charged them with using the device to "diagnose" the diseases, which they protest that Dr. Tang does not do and the device is incapable of doing, and that the IDE states that the device is an "indicator"and that was how they used it.

This argument fails to address the fundamental issue, which is that the Investigational Plan contains no provisions for using the devices, along with the ampules, to check patients for various diseases (such as cancer, HIV, and hepatitis), whether that is called "diagnosing" or "indicating."[20] The IDE does state that the device is an "indicator," which "indicates whether a person's energy balanced," *see, e.g.*, Def. Exh. M, Investigational Plan at 29; but, the IDE is very specific that the sole use of this "indicator" device under the diabetes study was to collect the conductance data from the 70 "points" related to diabetes.[21] Thus, the device could be used only to study whether the device could "indicate" whether a patient was insulin dependent, by comparing the conductance data gathered with the device to the subject's blood glucose reading.[22]

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[20] The Investigational Plan does not make any reference to the use of the device to check for the diseases mentioned, or the use of the device with the attachment of the ampules of medicines and solutions. *See supra,* at 9-11; Def. Exh. M (no mention of the ampules is made in the Methodology section, Components section, Manufacturing Process, Description of Device, Investigational Plan or IDE supplement).

[21] Those "points" are not diseases, but areas on the body correlated with "meridian fields." *See* Appendix B to IDE; *see also* Tang Dep., at 247-248 (Dr. Tang admitted that the device does not prompt her to check for diseases).

[22] Even Biosource's James Clark testified that the device is to be used to measure skin conductance at various points on the body to differentiate insulin-dependant diabetics from non-insulin dependent diabetics. *See* James Clark Dep., at 42-43. Likewise, the Informed Consent Form, that Century Clinic had each patient sign before using the LISTEN System device, states clearly that the patient is to be a participant in a study "to determine if the conductance

2. *"Practicing" with the LISTEN System devices*

Century Clinic also argues that they could use the devices without following the Investigational Plan because they were "practicing" with the devices in the "pre-research" phase before being chosen as investigators. *See, e.g.,* Tang Dep., at 46-47; 149-154. According to both Century Clinic and Biosource, this "pre-research use" of the devices was permitted because the Investigational Plan provided for "training" of investigators. *See, e.g., id.;* Ellingwood Dep., at 27, 90; Willis Clark Dep., at 17, 11.[23]

However, nowhere does the training described in the IDE state that the devices may be used without following the Investigational Plan and the IDE regulations, as "practice." *See* Def. Exh. M. at 54-55; *supra* at 10-11; *see also* IDE

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values and the items obtained through the conductance tests will correlate to the data obtained from the blood tests about carbohydrate metabolism." *See* Def. Exh. M, Appendix C (Informed Consent Form).

[23] To support its claim that the IDE permitted them to "practice" without following the Investigational Plan, Century Clinic submitted a memorandum dated September 27, 1993, from William F. McCormick to James Clark stating that Century Clinic could use the LISTEN System to practice on patients without recording the data. *See* Def. Exh. P. This document was provided for the record after the fact, after counsel for the government repeatedly questioned Herbert Ellingwood where any written document stated that "training" equaled "practice" without keeping records. *See* Ellingwood Dep., at 83-87. This alleged agreement between the two parties was not submitted to FDA for its concurrence. Willis Clark, the study monitor, testified that he is not aware of any communication from FDA concerning the "practice" use, i.e., that "practice" on patients was permissible. *See* Willis Clark Dep., at 90.

James Clark also testified that Biosource did not communicate with the IRB that human subjects would be practiced on with the device, that patients would not be told that they were being tested for practicing purposes, and that such practice did not follow the research protocol. *See* James Clark Dep. at 82.

Supplement, ¶¶ 7, at 21.[24] Rather, the IDE provides for *training*, requiring--as does the Research Agreement dated September 25, 1993, between Biosource and Century Clinic--that in addition to attending the training, the *investigator* submit a certain number of case studies following the research protocol. *See* Def. Exh. M, Appendix H; *see also* Def. Exh. P. These sections provide without question for use of the device in accordance with the protocol and the regulations.

Further, even if the training period could be construed to permit "practice," the manner in which defendants used the devices could not be considered "practice" for the diabetes study. Defendants would not need to, nor would it be permissible to, test patients for various diseases, with the ampules of solutions related to HIV, hepatitis, and herpes, to prepare for the diabetes study.[25]

Morever, there were no parameters for determining whether this "practice" would lead to the desired result--better skills for the IDE study; no data was collected and there was no regular review of the investigators' technique. Even Dr. Tang could not explain how a user of the device could determine whether he or she was progressing during practice, admitting

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[24] Herbert Ellingwood, the Clinic's attorney, admitted that the Investigational Plan does not refer to the word "practice." *See* Ellingwood Dep., at 82.

[25] While Dr. Tang alleged that she used the device just to "practice," she also testified that she used the device on repeat patients who "requested" it and on new patients where needed. *See* Tang Dep., at 99-100; 209. It is untenable that a device used to "practice" for a data collection study would be either requested or needed by patients.

that the employees at the Clinic did not evaluate one another. *Id.* at 170-171; *see also* Carlson Dep., at 55-56.[26]

And, while defendants claim that the requirements of the IDE regulations and Investigational Plan were inapplicable to them because they were not yet chosen as clinical investigators,[27] they obtained the unapproved device--which is only permitted of an investigator participating in an investigation, 21 C.F.R. § 812.43(b)--and signed an *investigator* agreement, as required by 21 C.F.R. § 812.43. This agreement, which FDA informed James Clark by letter dated September 10, 1993, must be obtained of investigators in the study, requires, among other things, that the "investigator" conduct the investigation in accordance with the IDE and IDE regulations. Dr. Tang and the other employees at the Clinic had their curriculum vitae submitted to Biosource under this agreement, which they signed.

Century Clinic also required their patients to sign the Informed Consent Forms to be part of the investigational study, as required by 21 C.F.R. § 812.100 and Part 50. *See, e.g.,* Tang Dep., at 52. These Informed Consent Forms, one of which Investigator Ritter was required to sign, state that the patient understands he or she is part of a "study of carbohydrate metabolism," to study whether the LISTEN System is "as safe and effective as the glucose tolerance blood test in detecting the

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[26] Willis Clark testified that he visited Century Clinic as an IRB monitor only once, in March 1994, nearly four months after the Level 1 training given to Century Clinic employees in November 1993. Willis Clark Dep., at 42, 47, 61. He admitted that the Clinic did not submit any reports to him in his capacity as monitor during the four month period. He also admitted that he completed a "monitor report form" on December 1, 1993, without actually visiting the Clinic and based his observations on a phone call. *Id.* at 93-94.

[27] *See, e.g.,* Tang Dep., at 152; Ellingwood Dep., at 90; Century Clinic's Reply Memorandum, at 23-24.

carbohydrate metabolism problem of diabetes mellitus." *See* Century Clinic Informed Consent Form.[28]

In sum, the Biosource IDE does not provide that the devices can be used, without following the protocol, or the IDE regulations, to "practice" on patients. The IDE regulations do not permit persons other than clinical investigators following a research protocol to use investigational devices. *See, supra,* at 6-8. Finally, using the device to test for various diseases, with the ampules, is not "practice" (were it allowed) for a diabetes data gathering study.

III. *STANDARD OF REVIEW*

The Defendants attack FDA's evidence as "unsworn testimony" and "unauthenticated exhibits," and allege that FDA has not proven--by clear and convincing evidence--that Century Clinic violated the terms of the Consent Decree. *See* Century Clinic's Memorandum in Opposition to FDA's Notice of Non-Compliance, at 20, and n. 55.[29] FDA has submitted a number of

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[28] Dr. Tang admitted that the Informed Consent Form that the Clinic requires patients to sign does not state that the LISTEN System device is being used to "practice" on the patient. *See* Tang Dep., at 165-166, 185-186. However, Century Clinic claims that patients are informed that the Clinic is practicing on them with the investigational devices. When Dr. Tang examined Investigator Ritter, she did not tell her that she was practicing on her, and even stated that it was illegal to use the device in this country unless it was being used *for research*, which is why the Consent Form had to be signed. *See* Undercover Investigation Transcript, at 7.

[29] Defendants' objections to FDA's failure to permit discovery in this proceeding are unwarranted. The Consent Decree sets forth the procedures to which the parties agreed. The procedures provide only that FDA will provide written notice of alleged violations, that Century Clinic can challenge those determinations in writing and orally, and that FDA would review the material Century Clinic submitted to determine whether to affirm its conclusions. Nowhere does the Decree provide for depositions or other forms of discovery. *See* Consent Decree at ¶ 10.

documents, including written summaries of two investigations and a transcript of conversations held between Dr. Tang and the investigator, Beverly Ritter, during the undercover investigation. *See* n. 7, at 4.

Five FDA investigators visited Century Clinic and interviewed the employees at the Clinic, as credentialed federal employees.[30] Defendants' charges that the FDA investigators completely misquoted them, and that the transcript of the undercover tape is inaccurate because words have been improperly inserted or left out, are not substantiated. Further, even though the transcript indicates that the tape was inaudible in sections, the transcript unmistakably establishes that Dr. Tang tested Investigator Ritter for a multitude of diseases and abnormalities with the device, using the ampules, which was not a use permitted by the carbohydrate metabolism study. In addition, during depositions (that Century Clinic insisted on taking of their own witnesses),[31] Dr. Tang and others *admitted* that the devices were used for what they called "practice," without following the protocol in the IDE, with the ampules of solutions, and without recording data required by the IDE regulations.

Based on the evidence, I find that the District has sustained its burden of establishing that Century Clinic violated the terms

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[30] Century Clinic questions these investigators' credibility, given that FDA did not submit to depositions, and skill and experience, alleging that the investigators were not competent to determine when Dr. Tang was "diagnosing" patients. These assertions are without merit. As already noted, the procedures to which the parties agreed did not include depositions, and whether Dr. Tang actually did or could diagnose the patients is irrelevant to the charges that she and others used the device in a manner completely unrelated to the IDE. (Even so, one of the FDA investigators was an M.D.).

[31] Century Clinic's witnesses have provided conflicting versions of events. In addition, personnel at the Clinic have altered their own statements.

of the Consent Decree, whether the standard of proof is a preponderance of the evidence or clear and convincing evidence.[32] Under the standard of clear and convincing evidence applied in a judicial civil contempt hearing, FDA would be charged with establishing that defendants failed to comply with a specific and definite court order and that the facts alleged are "highly probable."

As this opinion makes clear, defendants failed to comply with the specific terms of the Consent Decree. The Consent Decree explicitly prohibited, among other things, the use of the LISTEN System device unless a PMA or IDE permitted defendants' use of the device.

Defendants bear the burden of showing why they were unable to comply and must establish that they took every reasonable step to comply. *See, e.g., Stone v. City and County of San Francisco,* 968 F.2d 850, 856 (9th Cir. 1992). Defendants have not presented any evidence that establishes why they were *unable* to comply with the Decree or that supports that they took "all reasonable steps" to comply.[33]

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[32] I do not need to reach the issue of which standard is applicable, given that I find that FDA has proven its charges even under the judicial civil contempt standard of "clear and convincing" evidence. However, I note that this action is not a judicial "contempt" action, but the administrative procedure to which both parties agreed for the assessment of "penalty payments," *see* Consent Decree, at ¶¶10, for violations of the Decree. Therefore, I note that it appears that the preponderance of the evidence standard associated with civil money penalties is appropriate to this action. *See United States v. F/V Repulse,* 688 F.2d 1283, 1284 (9th Cir. 1982).

[33] In fact, Herbert Ellingwood, Century Clinic's in house counsel, seemed to suggest that the Clinic's responsibility was to follow whatever the sponsor/monitor told them to do. *See, e.g.,* Ellingwood Dep., at 27-28. Mr. Ellingwood also admitted that the Clinic did not consult FDA whether it was permissible for them to "practice" with the devices under the IDE. *Id.* at 114, 155. Dr. Tang stated she did not even carefully read the IDE, *see*

Rather, defendants raise defenses to civil contempt, arguing that the terms of the Consent Decree were "vague" and that they have "substantially complied" with the Decree.

As already noted, however, the Consent Decree specifically mentioned the LISTEN System by name, enjoining Century Clinic's use unless an IDE or PMA allowed such use. No such IDE or PMA permitted the use defendants made of these devices. The Consent Decree was explicit, not vague.

Defendants also have not established that they have "substantially complied" with the Decree. Defendants suggest that their noncompliances, if they occurred, were mere recordkeeping technicalities or "procedural niceties" and that such "technical" violations show that they substantially complied with the Consent Decree. Contrary to Century Clinic's characterizations, using the devices without regard to the IDE and requirements of the IDE regulations are not "technical" violations. Defendants' use of the devices in the manner described in this opinion--which was the very activity that the Consent Decree was intended to enjoin--does not amount to "substantial compliance" with the Decree.

IV. *THE PENALTY*

Century Clinic challenges the amount of the penalty the District is seeking. The Consent Decree clearly provides that the defendants "shall pay ... $200,000.00 per violation of this Decree ... . Each individual violative device shall constitute only one violation." Consent Decree, ¶¶10. Century Clinic entered into this Decree, agreeing to these terms, and the Decree was entered by the Court. The terms of the agreement, therefore, apply. *See, e.g., United States v. Armour & Co.*, 402 U.S. 673, 681-82 (1971).

Tang., Dep., at 149, also noting--regarding her "practice" use--that she had to "take peoples words. You cannot distrust everybody." *Id.* at 154.

There is no question that two LISTEN System devices were located on the premises of Century Clinic--one in Dr. Tang's office, a second in Teresita O'Gorman's examination room--and that both were used, on many of the Clinic's patients, without following the Investigational Plan in the IDE. *See, supra,* at 12-20.

Mr. Herbert Ellingwood testified that the Clinic purchased two LISTEN System devices from Biosource. *See* Ellingwood Dep., at 21, 95, 130.

Dr. Keith Carlson, an M.D. employed by the Clinic, testified that he had seen the LISTEN System devices used by both Dr. Tang and Teresita Alix-O'Gorman. *See* Carlson Dep., at 75-76; *see also* James Clark Dep., at 60.

Willis Clark testified that he observed the LISTEN System devices in use by four Century Clinic employees in March 1994. He indicated that the defendants used the metal plate with ampules of medicines and solutions. *See* Willis Clark Dep., at 43-44, 49, 60; *see also* Def. Exh. R. and Def. Exh. T.

Ms. Delora Cantin, a back-up technician at the Clinic, told FDA investigators that she has seen Ms. O'Gorman testing patients with the LISTEN System devices during evaluation and subsequent treatment. *See* April 11, 1994, Memorandum at 8. She also indicated that homeopathic drug ampules are kept in Dr. Tang's office, and that she must go there to obtain them for practice (one device is located outside of Dr. Tang's office). *Id.* at 9.

Finally, Teresita O'Gorman indicated to FDA investigators that she uses the LISTEN System occasionally on a patient. Herbert Ellingwood had stated she probably uses it more than anyone at the Clinic. *See id.*, at 9.

V. *CONCLUSION*

In conclusion, the Biosource IDE is very specific for the use of the LISTEN System as a data acquisition device for diabetes research. The IDE conditionally approved by FDA, among other things, required that an investigator collect conductance data from the 70 points and compare that data to blood glucose levels for the patient. As the use made by Century Clinic of the two LISTEN System devices at the Clinic in no way resembles the use permitted by the conditionally approved Biosource IDE under the IDE regulations, I affirm the District's finding that Century Clinic's use of the two devices violated the Consent Decree. The penalty of $400,000.00 is therefore affirmed.

/s/ Philip J. Frappaolo 12/11/95

PHILIP J. FRAPPAOLO
Deputy Director of Compliance
Center for Devices and
Radiological Health
United States Food and Drug
Administration

APPENDIX E

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 98-16373
D.C. No. CV-N-93-194-ECR (RAM)

UNITED STATES OF AMERICA,
Plaintiff-Appellee,

v.

CENTURY CLINIC, INC., a corporation,
and KATRINA TANG, H.M.D., an individual,
Defendants-Appellants,

and

YTWEN TANG, M.D., an individual,
Defendant.

FILED SEP 14 1998

ORDER

Before: T.G. NELSON, HAWKINS, and GRABER, Circuit Judges.

The petition for rehearing is DENIED.

APPENDIX F

Sec. 360j. General provisions respecting control of devices intended for human use

(a) General rule

Any requirement authorized by or under section 351, 352, 360, or 360i of this title applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 360c, 360d, or 360e of this title or under subsection (g) of this section, and any requirement established by or under section 351, 352, 360, or 360i of this title which is inconsistent with a requirement imposed on such device under section 360d or 360e of this title or under subsection (g) of this section shall not apply to such device.

(b) Custom devices

Sections 360d and 360e of this title do not apply to any device which, in order to comply with the order of an individual physician or dentist (or any other specially qualified person designated under regulations promulgated by the Secretary after an opportunity for an oral hearing) necessarily deviates from an otherwise applicable performance standard or requirement prescribed by or under section 360e of this title if (1) the device is not generally available in finished form for purchase or for dispensing upon prescription and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and (2) such device -

(A)(i) is intended for use by an individual patient named in such order of such physician or dentist (or other specially qualified person so designated) and is to be made in a specific form for such patient, or

(ii) is intended to meet the special needs of such physician or dentist (or other specially qualified person so designated) in the course of the professional practice of such physician or dentist (or other specially qualified person so designated), and

(B) is not generally available to or generally used by other physicians or dentists (or other specially qualified persons so designated).

(c) Trade secrets

Any information reported to or otherwise obtained by the Secretary or his representative under section 360c, 360d, 360e, 360f, 360h, 360i, or 374 of this title or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 360d of this title for a device reclassified from class III to class II, except (1) in accordance with subsection (h) of this section, and (2) that such information may be disclosed to other officers or employees concerned with carrying out this chapter or when relevant in any proceeding under this chapter (other than section 360c or 360d of this title).

(d) Notices and findings

Each notice of proposed rulemaking under section 360c, 360d, 360e, 360f, 360h, or 360i of this title, or under this section, any other notice which is published in the Federal Register with respect to any other action taken under any such section and which states the reasons for such action, and each

publication of findings required to be made in connection with rulemaking under any such section shall set forth -

(1) the manner in which interested persons may examine data and other information on which the notice or findings is based, and

(2) the period within which interested persons may present their comments on the notice or findings (including the need therefor) orally or in writing, which period shall be at least sixty days but may not exceed ninety days unless the time is extended by the Secretary by a notice published in the Federal Register stating good cause therefor.

(e) Restricted devices

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use -

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board

recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

(f) Good manufacturing practice requirements

(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this chapter.

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall -

(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated;

(ii) afford opportunity for an oral hearing; and

(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2)(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe and shall -

(i) in the case of a petition for an exemption from a requirement, set forth the basis for the petitioner's determination that compliance with the requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this chapter,

(ii) in the case of a petition for a variance from a requirement, set forth the methods proposed to be used in, and the facilities and controls proposed to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, facilities, and controls prescribed by the requirement, and

(iii) contain such other information as the Secretary shall prescribe.

(B) The Secretary may refer to the advisory committee established under paragraph (3) any petition submitted under subparagraph (A). The advisory committee shall report its recommendations to the Secretary with respect to a petition referred to it within sixty days of the date of the petition's referral. Within sixty days after -

(i) the date the petition was submitted to the Secretary under subparagraph (A), or

(ii) if the petition was referred to an advisory committee, the expiration of the sixty-day period

beginning on the date the petition was referred to the advisory committee,

whichever occurs later, the Secretary shall by order either deny the petition or approve it.

(C) The Secretary may approve -

(i) a petition for an exemption for a device from a requirement if he determines that compliance with such requirement is not required to assure that the device will be safe and effective and otherwise in compliance with this chapter, and

(ii) a petition for a variance for a device from a requirement if he determines that the methods to be used in, and the facilities and controls to be used for, the manufacture, packing, storage, and installation of the device in lieu of the methods, controls, and facilities prescribed by the requirement are sufficient to assure that the device will be safe and effective and otherwise in compliance with this chapter.

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this chapter.

(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under

paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). The advisory committee shall be composed of nine members as follows:

(A) Three of the members shall be appointed from persons who are officers or employees of any State or local government or of the Federal Government.

(B) Two of the members shall be appointed from persons who are representative of interests of the device manufacturing industry; two of the members shall be appointed from persons who are representative of the interests of physicians and other health professionals; and two of the members shall be representative of the interests of the general public.

Members of the advisory committee who are not officers or employees of the United States, while attending conferences or meetings of the committee or otherwise engaged in its business, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate one of the members of the advisory committee to serve as its chairman. The Secretary shall furnish the advisory committee with clerical and other assistance. Section 14 of the Federal Advisory Committee Act shall not apply with respect to the duration of the advisory committee established under this paragraph.

(g) Exemption for devices for investigational use

(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)(A) The Secretary shall, within the one hundred and twenty-day period beginning on May 28, 1976, by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 352, 360, 360d, 360e, 360f, 360i, or 379e of this title or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

(C) Procedures and conditions prescribed pursuant to subparagraph (A) for an exemption may appropriately vary depending on (i) the scope and duration of clinical testing to be conducted under such exemption, (ii) the number of human subjects that are to be involved in such testing, (iii) the need to permit changes to be made in the device subject to the exemption during testing conducted in accordance with a clinical testing plan required under paragraph (3)(A), and (iv) whether the clinical testing of such device is for the purpose of developing data to obtain approval for the commercial distribution of such device.

(3) Procedures and conditions prescribed pursuant to paragraph (2)(A) shall require, as a condition to the exemption of any device to be the subject of testing involving human subjects, that the person applying for the exemption -

(A) submit a plan for any proposed clinical testing of the device and a report of prior investigations of the device (including, where appropriate, tests on animals) adequate to justify the proposed clinical testing -

(i) to the local institutional review committee which has been established in accordance with regulations of the Secretary to supervise clinical testing of devices in the facilities where the proposed clinical testing is to be conducted, or

(ii) to the Secretary, if -

(I) no such committee exists, or

(II) the Secretary finds that the process of review by such committee is inadequate (whether or not the

plan for such testing has been approved by such committee),

for review for adequacy to justify the commencement of such testing; and, unless the plan and report are submitted to the Secretary, submit to the Secretary a summary of the plan and a report of prior investigations of the device (including, where appropriate, tests on animals);

(B) promptly notify the Secretary (under such circumstances and in such manner as the Secretary prescribes) of approval by a local institutional review committee of any clinical testing plan submitted to it in accordance with subparagraph (A);

(C) in the case of a device to be distributed to investigators for testing, obtain signed agreements from each of such investigators that any testing of the device involving human subjects will be under such investigator's supervision and in accordance with subparagraph (D) and submit such agreements to the Secretary; and

(D) assure that informed consent will be obtained from each human subject (or his representative) of proposed clinical testing involving such device, except where subject to such conditions as the Secretary may prescribe, the investigator conducting or supervising the proposed clinical testing of the device determines in writing that there exists a life threatening situation involving the human subject of such testing which necessitates the use of such device and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from his representative.

The determination required by subparagraph (D) shall be concurred in by a licensed physician who is not involved in the

testing of the human subject with respect to which such determination is made unless immediate use of the device is required to save the life of the human subject of such testing and there is not sufficient time to obtain such concurrence.

(4)(A) An application, submitted in accordance with the procedures prescribed by regulations under paragraph (2), for an exemption for a device (other than an exemption from section 360f of this title) shall be deemed approved on the thirtieth day after the submission of the application to the Secretary unless on or before such day the Secretary by order disapproves the application and notifies the applicant of the disapproval of the application.

(B) The Secretary may disapprove an application only if he finds that the investigation with respect to which the application is submitted does not conform to procedures and conditions prescribed under regulations under paragraph (2). Such a notification shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application and afford the applicant opportunity for an informal hearing on the disapproval order.

(5) The Secretary may by order withdraw an exemption granted under this subsection for a device if the Secretary determines that the conditions applicable to the device under this subsection for such exemption are not met. Such an order may be issued only after opportunity for an informal hearing, except that such an order may be issued before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption with respect to which the order is to be issued will result in an unreasonable risk to the public health.

(6)(A) Not later than 1 year after November 21, 1997, the Secretary shall by regulation establish, with respect to a device

for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit -

(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

(ii) changes or modifications to clinical protocols that do not affect -

(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

(III) the rights, safety, or welfare of the human subjects involved in the investigation.

(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if -

(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device.

(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Any such agreement shall not be changed, except -

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary

has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.

APPENDIX G

STUART GERSON
Assistant Attorney General
EUGENE M. THIROLF
DRAKE CUTINI
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
Telephone: (202) 307-0044

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEVADA

Civil No. CV-N-93-194-ECR

UNITED STATES OF AMERICA,

Plaintiff,

v.

CENTURY CLINIC, INC., a corporation,

and

YIWEN TANG, M.D., an individual,

and

KATRINA TANG, H.M.D. an individual,

Defendants.

FILED MAR 23 1993
ENTERED & SERVED MAR 24 1993

CONSENT DECREE OF *PERMANENT INJUNCTION*

Plaintiff, United States of America, having filed a complaint for injunction herewith against Century Clinic, Inc., a corporation, Yiwen Tang, M.D., an individual, and Katrina Tang, H.M.D., an individual, and these defendants having appeared and having consented to entry of this Decree without contest and before any testimony has been taken; and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:

1. This Court has jurisdiction over the subject matter and over all the parties to this action.

2. The complaint for injunction states a claim for relief against the defendants under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 301 *et. seq.*

3. The defendants Century Clinic, Inc., Yiwen Tang, M.D., and Katrina Tang, H.M.D., and each of their officers, agents, servants, employees, attorneys, and each of those persons in active concert or participation with them who receive actual notice of the contents of this Consent Decree by personal service or otherwise, are hereby permanently enjoined from directly or indirectly doing or causing to be done any of the following acts:

A. Manufacturing, labeling, packaging, promoting, distributing, importing, or using the EAV Dermatron, the Malcolm Rae, the Prophyle, or any product having or purporting to have a similar appearance, name or intended use (including but not limited to the products known as the Interro, the Accu-Path 1000, the Bio-Path, the Listen System, the Computronix Accupro II, the E.P.F.X. biofeedback system, and the Bio-Cellular Analyzer II) unless and until: (1) there is in

effect an approved application for premarket approval (PMA), pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption (IDE), pursuant to 21 U.S.C. § 360j(g), that authorizes the defendants' use of such product(s); and (2) other FDA approval of such products as required by the Act and implementing regulations has been obtained.

B. Manufacturing, labeling, packaging, promoting, distributing, or using Cook's Slim Diode, Wayne Cook's Pocket Diode, or any or any product having or purporting to have a similar appearance, name or intended use, unless and until: (1) there is in effect an approved PMA pursuant to 21 U.S.C. § 360e, or an approved IDE pursuant to 21 U.S.C. § 360j(g), that authorizes the defendants' use of such product(s); and (2) other FDA approval of such products as required by the Act and implementing regulations has been obtained.

C. Manufacturing, labeling, packaging, promoting, distributing, importing, or using through any means any other product that is a medical device under 21 U.S.C. § 321(h), if that product is misbranded or is otherwise in violation of any provision of the Act.

D. Causing any product that is a medical device under 21 U.S.C. § 321(h) to be misbranded or otherwise to be in violation of any provision of the Act.

4. Within three business days of the entry of this Decree, defendants shall surrender to the FDA all unapproved devices in their possession, custody, or control, meeting the descriptions in subparagraphs A and B of paragraph 3 of this Decree, and all promotional materials (including, but not limited to, video-tapes, audio-tapes, labeling, and all other written materials) relating to or in any way mentioning those unapproved devices.

5. Within ten days of the date of entry of this Decree the defendants shall serve a copy of this Decree, by certified mail, return receipt requested, upon each of their officers, agents, servants, employees, attorneys, and upon those persons in active concert or participation with them who are not employed at Century Clinic. Service can be accomplished by personal delivery of a copy of this Decree to all employees of Century Clinic; the employees personally served shall provide written acknowledgment of service.

6. Within thirty days of the date of the entry of this Decree, each of the defendants shall provide to the FDA District Director, San Francisco Office, 50 United Nations Plaza, San Francisco, California, 94102, an affidavit, identifying all persons upon whom this Decree has been served and evidencing their compliance with paragraph 5 of the Decree by providing copies of all such certified mail receipts or acknowledgment of service.

7. In order to ensure continuing compliance with the terms of this Decree, investigators from the FDA shall be authorized to make inspections of defendants' facilities, on a reasonable basis, as FDA deems necessary, including all equipment, materials, and products therein, to take photographs as necessary and to examine and copy all records relating to the receipt, processing, packing, labeling, promoting, advertising, holding, and distribution of all medical devices meeting the descriptions in subparagraphs A and B of paragraph 3 of this Decree. The FDA shall also be authorized to inspect and copy all relevant records; in addition, to the extent necessary to ensure compliance with this Decree, FDA may inspect patient records with the patient names redacted and such redaction shall occur prior to the inspection to the fullest extent practicable. The defendants shall provide such names to the Court under seal immediately upon request by the FDA, and unless defendants object, as discussed in the next sentence,

FDA shall be given access to the patients' names by the Court upon FDA's request to the Court. If defendants object to FDA's request, FDA's request shall be decided by the Court under applicable law; it is the position of FDA and the United States that patient names and records are available under Federal law and the issue, including any issue of confidentiality or privilege, is to be determined by federal law, and it is the position of the defendants that a state doctor-patient privilege applies and that state law precludes physicians or their employees from releasing patient information without the patient's consent. Such patient records shall be retained in a confidential manner and disclosed only to the extent necessary to ensure compliance with this Decree, and such records shall be returned to defendants, after any appropriate copying, within ten business days. Such inspections shall be conducted at reasonable times and in a reasonable manner which respects patient privacy. Such inspections shall be authorized upon presentation of a copy of this Decree and appropriate credentials. Devices in violation of this Decree may be detained during such an inspection in compliance with 21 U.S.C. § 334(g). Such inspection and patient record access authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, *e.g.*, 21 U.S.C. § 374, or the regulations, *e.g.*, 21 C.F.R. § 812.145, or any other applicable provision of law granting such authority. Refusal to permit such inspection shall constitute a violation of this Decree, unless a Court holds that such refusal is not a violation of this Decree. FDA's decisions and conduct with regard to inspection under this paragraph are subject to judicial review under paragraph 11.

8. The defendants shall reimburse the FDA in accordance with this paragraph for the costs of any FDA inspections, supervision, analyses, or examinations reasonably necessary to evaluate the defendants' compliance with this Decree at the rate

of $45.00 per hour or fraction thereof per representative for inspection work; $54.00 per hour or fraction thereof per representative for analytical work; $ 0.25 cents per mile or air fare at the government contract rate for travel expenses; and $76.00 per day for subsistence expenses where necessary. Defendants shall be responsible for such reimbursement for two such inspections per calendar year provided no violations of this Decree are found; defendants shall be responsible for such reimbursement for any inspections where violations of this Decree are found.

9. The defendants shall notify the FDA District Director, San Francisco District Office, 50 United Nations Plaza, San Francisco, California, 94102, at least ten days before any change in ownership or character of their business that may affect compliance obligations arising out of this Decree, such as reorganization, dissolution, assignment, or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure of Century Clinic, or the sale or assignment of any business assets, such as buildings, equipment or inventory. Defendants shall serve a copy of this Decree on any newly created successor or assign within five days of such occurrence, and shall furnish plaintiff an affidavit of compliance within fifteen days of such occurrence, in accordance with the provisions of paragraph 6 above.

10. To deter any violations of this Decree, the defendants shall pay to the United States $200,000.00 per violation of this Decree; all defendants are jointly and severally liable for this amount per violation, except that if a defendant is operating wholly independently, then this $200,000.00 per violation liability for that defendant shall be individual liability. Each individual violative device shall constitute only one violation; the labeling for such devices does not constitute separate violation(s). The defendants shall, simultaneously with the

filing of this Decree, obtain a Certificate of Deposit (CD) in the amount of $200,000.00 from an FDIC insured bank and place it into an escrow account in the same bank; the escrow agreement for the CD shall direct that the CD is to be payable to the United States upon the conditions established in this paragraph. The language of the escrow agreement must be approved by counsel for the United States prior to entry of this Decree. Such escrow amount shall be available to the United States to satisfy any penalty payments under this paragraph. Once payment is made under such escrow agreement, or if the FDA notifies defendants of more than one violation, defendants shall increase the escrow amount to ensure that it provides sufficient funds to ensure $200,000.00 per violation. Upon written notice from the FDA that any defendant is in violation of this Decree, such defendant(s) shall have 10 days from the receipt of said notice to challenge the FDA determination or otherwise forfeit the payment of $200,000.00 per violation. If the FDA determination is challenged, defendants shall have a full opportunity to submit written materials on their behalf, and to make an oral presentation, to the FDA. FDA shall review such material and determine whether to affirm its initial finding that defendants have violated the Decree. If FDA affirms its initial decision, that determination shall be subject to review by the District Court under the standard of review set forth in the next paragraph. The escrow amount shall be paid to the United States if it is finally determined, after any appeal, that the Decree was violated. The penalty under this paragraph shall be in addition to, and not in lieu of, any penalty for criminal contempt that the Court may impose, and shall not bar the United States or FDA from pursuing any other criminal remedy it may have for the same conduct.

11. FDA's decisions under this Decree shall be reviewed under the arbitrary and capricious review standard of 5 U.S.C. § 706(2)(A), and such review shall be based upon the full

administrative record developed before the FDA and on which it made its decision. FDA's decisions with respect to an application for a PMA or an IDE by defendants shall be subject to review as specified in the Act, 21 U.S.C. § 360g(a).

12. Within two days of the entry of this Decree, defendants will dismiss, with prejudice, their motions for return of seized property and other relief, *In re Search of Century Clinic,* No CV-91-231-HDM, and their complaint in *Tang, et al. v. Sullivan,* No. CV-N-91-041-HDM, both pending in the United States District Court for the District of Nevada. In addition, Defendants consent to the destruction of all drugs, devices, and promotional materials seized by the government during searches of Century Clinic conducted on September 6 and October 25, 1990, except that all devices meeting the descriptions under paragraph 3A and 3B shall be retained for 6 months to enable defendants to seek approval of an IDE for these devices; if such an IDE is not obtained within six months of the date of this Decree, such devices shall be destroyed. The United States will, within two days of the entry of this Decree, return to the Defendants all books, records, checks, and other items and materials not so destroyed.

13. Based upon defendants' representations, it is the understanding of the parties that defendant Yiwen Tang is no longer practicing medicine or connected with the operations of Century Clinic in any manner. For this reason, none of the provisions of this Decree applies to Yiwen Tang unless he in some manner begins the practice of medicine or becomes associated with the operations of Century Clinic, in which case all terms of this Decree are fully applicable to him.

14. This Court retains jurisdiction over this action for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be hereafter necessary or appropriate. If the defendants maintain a state of

continuous compliance with the terms of this Decree for a period of three years from the date of the entry of this Decree, defendants may move to vacate this order and the government will not oppose.

15. On the date of entry of this Decree, the defendants shall pay to the United States Food and Drug Administration a sum of $65,000.00 as reimbursement for actual costs incurred in the investigation of this matter, said sum to constitute a debt immediately due and owed to the United States. The money shall be paid by check to be delivered to the FDA District Director, San Francisco Office, 50 United Nations Plaza, San Francisco, California, 94102.

16. Except as provided in paragraph 15, the parties shall bear their own costs and attorneys fees in connection with this action.

SO ORDERED this 22nd day of March, 1992.

/s/ Edward C. Reed

United States District Judge

We hereby consent to the entry of the foregoing Decree.

FOR THE DEFENDANTS

/s/ William F. McCormick

The Century Clinic, Inc.
by William F. McCormick,
President

/s/ Katrina Tang

Katrina Tang
Individually

/s/ Wm. Bradford Reynolds

Wm Bradford Reynolds
Dickstein, Shapiro & Morin
2101 L. Street, N.W.
Washington, D.C. 20037-
1526
(202) 785-9700

Attorney for Defendants

/s/ N. Patrick Flanagan

N. Patrick Flanagan
Beckley, Singleton, DeLanoy,
Jemison and List, Chtd.
100 West Liberty Street
Suite 700
Reno, Nevada 89501
(702) 323-8866

Attorney for Defendants

FOR THE PLAINTIFF

STUART M. GERSON
Assistant Attorney General
U.S. Department of Justice

MONTE N. STEWART
United States Attorney
District of Nevada

/s/ Shirley Smith

Assistant U.S. Attorney

/s/ Eugene M. Thirolf

Director
Drake Cutini
Trial Attorney
Office of Consumer
Litigation
P.O. Box 386
Washington D.C. 20044
(202) 307-0044

Attorneys for Plaintiff

OF COUNSEL:
MARGARET JANE PORTER
Chief Counsel

ERIC M. BLUMBERG
Chief Counsel for
Enforcement
MICHAEL M. LANDA
Associate Chief Counsel
U.S. Food and Drug
Administration
5600 Fishers Lane
Rockville, MD 20857